EFFECT OF TOPICAL OXYGEN THERAPY ON WOUND HEALING AMONG PATIENTS WITH DIABETIC FOOT ULCER AT SELECTED HOSPITAL, COIMBATORE

SINDHUJA.B

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MASTER OF SCIENCE IN NURSING

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This is to certify that the dissertation entitled **"Effect of Topical Oxygen Therapy on Wound healing Among patients with Diabetic foot ulcer at Selected Hospital, Coimbatore"** is a bonafide work done by **Sindhuja.B College of Nursing, Sri Ramakrishna Institute of Paramedical Sciences** in partial fulfillment of the University rules and regulations for award of **M.Sc. Nursing Degree** under my guidance and supervision during the academic year **2016.**

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Abstract

The main aim of the present study was to assess the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer. The study was conducted at selected wards of Sri-Ramakrishna hospital. The research design used for the present study was true-experimental design.By using consecutive sampling technique 21 patients with diabetic foot ulcer were selected for the study. Glycosylated hemoglobin value was taken as the criteria to maintain homogeneity among the samples. The samples were randomly assigned to experimental (n=10) and the control group (n=11) respectively. The level of wound healing was assessed using Bates Jensen wound assessment tool(BWAT).Intervention was given to the experimental group for 30 minutes once daily for 10 days, whereas the control group received routine care .Post test was performed on the eleventh day with the same tool. Results showed that, the mean of experimental group and control group was 24.8 and 38.9 with the 't' value of 3.38 which was significant at ($p<0.01$).There was a significant improvement in the level of wound healing among patients with diabetic foot ulcer after implementation of topical oxygen therapy. Hence the study concluded that administration of topical oxygen therapy was found to be effective measure in treating diabetic foot ulcer.

INTRODUCTION

"It is the health that is the real wealth"

-Buddha

Health is a balanced condition of the living organism in which the integral, harmonious performance of the vital functions tends to the preservation of the organism and the normal development of the individual. The maintenance and promotion of health is achieved through different combination of physical, mental, and social well-being, together referred to as the health triangle.(National Wellness Institute ,2014)

Health and disease are logical, complex and multi-factorial. There are a lot of health issues that is common in many people across the globe. According to GlobalIssues.org, approximately 36 million people die each year from non-communicable disease including cardiovascular disease cancer and diabetes. (Brundtland, 2014)

Diabetes mellitus is one of the commonest cause for hospitalization.Diabetes mellitus is recognised as an epidemic in the Asian sub-continent affecting nearly more than 50 million in India alone. Diabetes is a disease of complication with decreasing the life span of diabetic patients. (Xiong ,2013)

Diabetes Mellitus is a chronic condition that occurs when the pancreas does not produce enough insulin (or) the body cannot effectively use the insulin it produces. Diabetes mellitus is classified into two broad categories: type 1, type 2 diabetes mellitus. (Tripathy, 2012)

Type 1 diabetes mellitus is characterized by loss of the insulin-producing beta cells of the islets of Langerhans in the pancreas, leading to insulin deficiency. This type can be further classified as immune-mediated or idiopathic. The majority of type 1 diabetes is of the immune-mediated nature, in which a T-cellmediated autoimmune attack leads to the loss of beta cells. (Albert & Zimmet, 2004).

Type 2 diabetes mellitus is characterized by insulin resistance, which may be combined with relatively reduced insulin secretion. The defective responsiveness of body tissues to insulin is believed to involve the insulin receptor. Type 2 diabetes mellitus is the most common type of diabetes mellitus. (American diabetes association, 2004)

Most of the diabetic patients report to health care facility with major complication of diabetic foot ulcer.Ulcers are the wounds (or)open sores that will not heal and been present for more than 3-4 weeks, result from changes in blood vessels and nerves of peripheral tissues that leads to subsequent amputation. These often appear to be more insidious and may occur with a greater intensity and severity than their peers without diabetes mellitus. (Jeffcoate, 2003)

The human foot has an intricate structure, similar to that of the wrist and hand, unlike the hands, the feet for a lifetime, average person walks 75,000 to 1,00,000 miles. It is not surprising that the feet undergoes stress. If a person with normal sensation feels discomfort in some part while walking, he will compensate by changing the way his foot touching the ground, transferring impact and pressure forces to another part.People with diabetes in whom the sensation may be diminished(or)lost the ordinary way of walking is where many foot problem begin with,

Effect on skin: skin – and the soft tissues immediately underneath the skinundergoes greater compression and shear loading than usual, thus explaining the onset of tissue damage so deeply correlated to traumatic ulceration processes. Besides this, skin of the diabetic foot suffers from loss of autonomic nervous control and consequently reduced hydration, making it less elastic and thus more vulnerable to the action of increased mechanical stress. (Davidson, 2002)

Effect on tendons and ligaments: protein glycosylation and the resulting collagen abnormalities lead to greater transversal section (i.e.) thickening of tendons and ligaments and a greater coefficient of elasticity. Particularly impacted by this process are plantar fascia and Achilles tendon. Both causes lead to an increased stiffness of those structures. (Davidson , 2002)

Effects on cartilage: similar to what happens to tendons and ligaments, cartilage changes its composition mainly due to the modification of collagen fibers, and this increases its stiffness and decreases the range of motion of all joints in the foot and ankle. (Davidson , 2002)

Effects on muscles: Diabetes mellitus causes severe damage to nerve conduction, thus causing a worsening in the management of the related muscle fibers. As a consequence, both intrinsic and extrinsic muscles of the foot-ankle complex are damaged in structure (reduction of muscle volume) and function (reduction of muscle strength). (Davidson, 2002)

Due to most of the above alterations, a significant imbalance of peripheral musculature and soft tissue occur in the foot which seriously alters its morphology and determines the onset of foot deformities. Most common deformities of the diabetic foot are represented by a high longitudinal arch (rigid caves foot), hammer toes and hallux valgus.

A study conducted on Global prevalence on diabetes, shows that the prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and to be 4.4% in 2030. India gets capital of diabetes in 2025, (i.e.) 25 million to 75 million in 2025. (WHO, 2009)

It is estimated that globally out of 382 million diabetes patients, 15% develop diabetic foot ulceration and 30% of admission are due to diabetic foot ulcer. (Sarah., et.al, 2009)

In India 33% of diabetic people develop foot ulcer. Out of lower limb amputation 85% are due to diabetes. Every 30 second a diabetic patient somewhere in the world looses lower limb. In Coimbatore district 15% of total diabetic population is affected with foot ulcer. (National diabetes statistics, 2011)

A study conducted in TamilNadu State between the period 2009 and 2010 shows that 19 percentage of population are at a risk of diabetes mellitus.
(Gupta ., et.al,2010)

The Hindu reports that 48 lakh people in Tamil Nadu have diabetes, with rural accounting for 7.8 per cent and urban 13.7 per cent. Around 2.8 lakh people have diabetes in Coimbatore district and 3.2 lakh people have pre-diabetes. (Mohan, 2010)

Almost 20% diabetics will develop a foot ulcer in their lifetime and almost one third of these are delayed in referral for care. Almost two third of all diabetic patients recently referred to a wound care clinic for non-healing foot wound who didnothavethebasisofdiabetic foot wound care applied to them. (Gayle, 1998)

Many persons with diabetes who undergo a lower extremity amputation, have an amputation of contra lateral legs within few years. This occurs not only because of peripheral neuropathy and peripheral vascular disease but also because of the remaining foot bears increased pressure and frequently develop ulceration and infection .(Chumber & Bal, 2010)

The major increase in mortality among diabetic patients observed over the past 20 years was considered to be due to the development of macro and micro vascular complications, including failure of the wound healing process. (Lewis 2014)

Wound healing is an innate mechanism of action that works reliably most of the time. A key feature of wound healing is stepwise repair of lost extracellular matrix (ECM) that forms the largest component of the dermal skin layer. Controlled and accurate rebuilding is essential to avoid under- or over-healing that may lead to various abnormalities. But in some cases, certain disorders or physiological insult disturbs the wound healing process. Diabetes mellitus is one such metabolic disorder that impedes the normal steps of the wound healing process. Many histopathological studies show a prolonged inflammatory phase in diabetic wounds, which causes a delay in the formation of mature granulation tissue and a parallel reduction in wound tensile strength. (Harold ,2007)

One critical parameter for wound healing is oxygen that is required for almost every step of the healing process.In wound healing, biochemical energy supply is a basic requirement. Oxygen is essential for the production of biological energy equivalents (e.g. adenosine triphosphate, ATP) in aerobic glycolysis, the citric

acid cycle, and the oxidation of fatty acids. Therefore, sufficient oxygenation of tissue is a prerequisite for adequate energy levels, which are essential for proper cellular function. (Global status report on health, 2014)

Topical oxygen therapies are designed to allow oxygen to enter the wound or skin via the external surface of the body rather than from capillaries within. The oxygen is therefore delivered directly to the wound and the systemic side effects are eliminated. (Daniel, 2010)

Treatment methods that deliver gaseous oxygen include enclosures around a limb or wound site that are flushed with pure gaseous oxygen. A major advantage of topical oxygen therapy is its independence of the wound's microcirculation. Other advantages are lower costs, the lower risk of oxygen toxicity, and the possibility of home treatment. (Looree.K , 2003)

1.1 Need for the study

171 million people worldwide have diabetes mellitus .Top 10 countries in numbers of sufferers include India, China, Russia, U.S.A, Japan, Brazil, Indonesia, Italy, Bangladesh .(Hindu,2015)

India with approximately 42 million cases is ranked first in the list of the ten nations most affected with diabetes. Among diabetes mellitus related complications, foot ulceration is the most common, affecting approximately 15% of diabetic patients during their lifetime. This can be attributed to several social and cultural practices such as barefoot walking, inadequate facilities for diabetes care and education, and poor socioeconomic conditions. Sporadic qualitative research suggests that diabetic foot ulceration has a profound social impact with patients reporting stigma, social isolation, loss of social role, and unemployment. (Anders, G.,et.al 2001)

Routine ulcer care, treatment of infections, amputations, and hospitalizations cost millions of rupees every year and place a tremendous burden on the health care system.In India it is estimated that diabetic foot problems is an expensive affair and an average individual spend about 50% of his income on diabetic problems. (Boulton, 2009).

Risk factors implicated in the development of diabetic foot ulcers are diabetic neuropathy, cigarette smoking, poor glycaemic control, and ischemia of small and large blood vessels. (Phipps, 1995)

The cornerstone of complex diabetic wound care is thorough surgical removal of unhealthy tissue (debridement). Devitalized skin, muscle and bone will be excised and deep tissue cultures sent to allow for optimization of antibiotic therapy. If debridement has resulted in exposure of important structures such as nerves, bones, tendons or joints then plastic surgical techniques may be required to close the wound. This may include local rearrangement of tissues (local flap), application of skin grafts or importing healthy tissue from a distant site utilizing microsurgical techniques (free flap.)In the case of infection specialists customize antibiotic therapy and endocrinologists optimize control of blood sugar.(Thanh Dinh, 2012)

To prevent such invasive procedures, a new modality of non-invasive topical oxygen therapy is used. Oxygen is well known to be required for wound healing. The enzymes involved in bacterial killing, collagen synthesis, angiogenesis and epithelialisation requires PO_2 levels in wound tissue ranging from 25 to 100 mmHg. (Schreml , 2010).

Oxygen is a critical component in the wound healing process and a lack of oxygen (hypoxia) results in poor or non-existent healing. Today several systems for the topical delivery of oxygen to wounds; these include oxygen emitting

dressings, oxygen tents or chambers, sub-dressing oxygen delivery systems and aqueous oxygen peroxide delivery systems.(National library of medicine, 2014)

The key multifaceted roles of oxygen in wound healing include the following,

Energy metabolism-Oxygen is the last electron acceptor for mitochondrial cytochrome oxidase leading to the production of highenergy phosphates that are required for multiple cellular functions. (Bryant, 1992)

Collagen synthesis and Neovascularization Oxygen is involved in the hydroxylation of proline and lysine in procollagen, which is crucial in collagen maturation .Although hypoxia is required to engender neovascularization, supplemental oxygen administration has been shown to sustain and accelerate vessel growth. Oxygen induces vascular endothelial growth factor (VEGF) mRNA levels in endothelial cells and macrophages in vivo. It may also facilitate wound contraction by triggering the differentiation of fibroblasts to myofibroblasts. (Luckman, 1995)

Topical oxygen therapy involves the application of oxygen to a cutaneous wound or ulcer. It is believed to facilitate diffusion of oxygen into the wound and thus improve blood supply and reduce tissue edema. It is relatively very low cost and reduces nearly 50 percentage of dressing costs. No pain, No side effects, makes surgical debridement unnecessary. (Feld Meier et al., 2005)

Considering the above facts, the researcher is interested to select topical oxygen therapy as intervention, in order to improve the level of wound healing among patients with diabetic foot ulcer.

1.2 Statement of the problem

Effect of Topical Oxygen Therapy on Wound Healing among Patients with Diabetic Foot Ulcer at Selected Hospital, Coimbatore.

1.3 Objectives of the study

1.3.1 To assess the level of wound healing among patients with diabetic foot ulcer.

1.3.2 To evaluate the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer.

1.3.3 To associate wound healing in relation to selected demographic variables among patients with diabetic foot ulcer.

1.4 Operational definition

1.4.1 Effect

It refers to an outcome produced by topical oxygen therapy on wound healing among patients with diabetic foot ulcer with Bates Jensen wound assessment tool (BWAT).

1.4.2 Topical oxygen therapy

Application of gaseous oxygen directly to a cutaneous wound for 30 minutes once daily for 10days.

1.4.3 Wound healing

Filling up of the wound with regenerative tissue which is measured in terms of reduction in Bates Jensen wound assessment score.

1.4.4 Patients with Diabetic foot ulcer

It refers to patients who are diagnosed to have high blood glucose levels admitted in hospital with a peripheral tissue ulcer.

1.5 Hypothesis

1.5.1 There will be a significant difference in the level of wound healing in experimental group and control group after administration of topical oxygen therapy.

1.5.2 There will be a significant association between the selected demographic variables and wound healing among patients with diabetic foot ulcer.

1.6 Conceptual framework

Conceptualization is a process of forming ideas which utilizes and forms a conceptual framework for the study. It is the abstract, logical structure which enables the researcher to link the findings to the nursing body of knowledge. A framework is the abstract of logical structure of meaning that guides the development of the study and the body of knowledge.

Conceptual framework used for this study is based on general system theory. Ludwig Von Bertalanffy (1968) introduced general system theory as a universal theory that could be applied to many field of study.

A system is a set of interacting identifiable parts or components and it depends on the quality and quantity of its input, throughput, output and feedback. Input consists of information, material or energy that enters the system. After the input is absorbed by the system, it is processed in a way useful to the system. This information is called throughput. Output from a system is energy, matter or information given out by the system is returned to the system as input.

Input

In the present study, input begins with establishing rapport to the patients with diabetic foot ulcer. In this phase the researcher collects the necessary information based on demographic data and assesses the level of wound healing status using Bates Jensen wound assessment tool (BWAT). Then the clients those who met the criteria were selected for providing topical oxygen therapy.

Throughput

It is the use of input such as energy matter and information for the maintenance of the homeostasis of the system. It is a series of action by which the system converts its energy input from the environment into products and services that are usable by the system. The process can be modified in response to feedback. Researcher in this study implemented topical oxygen therapy on patients with diabetic foot ulcer.

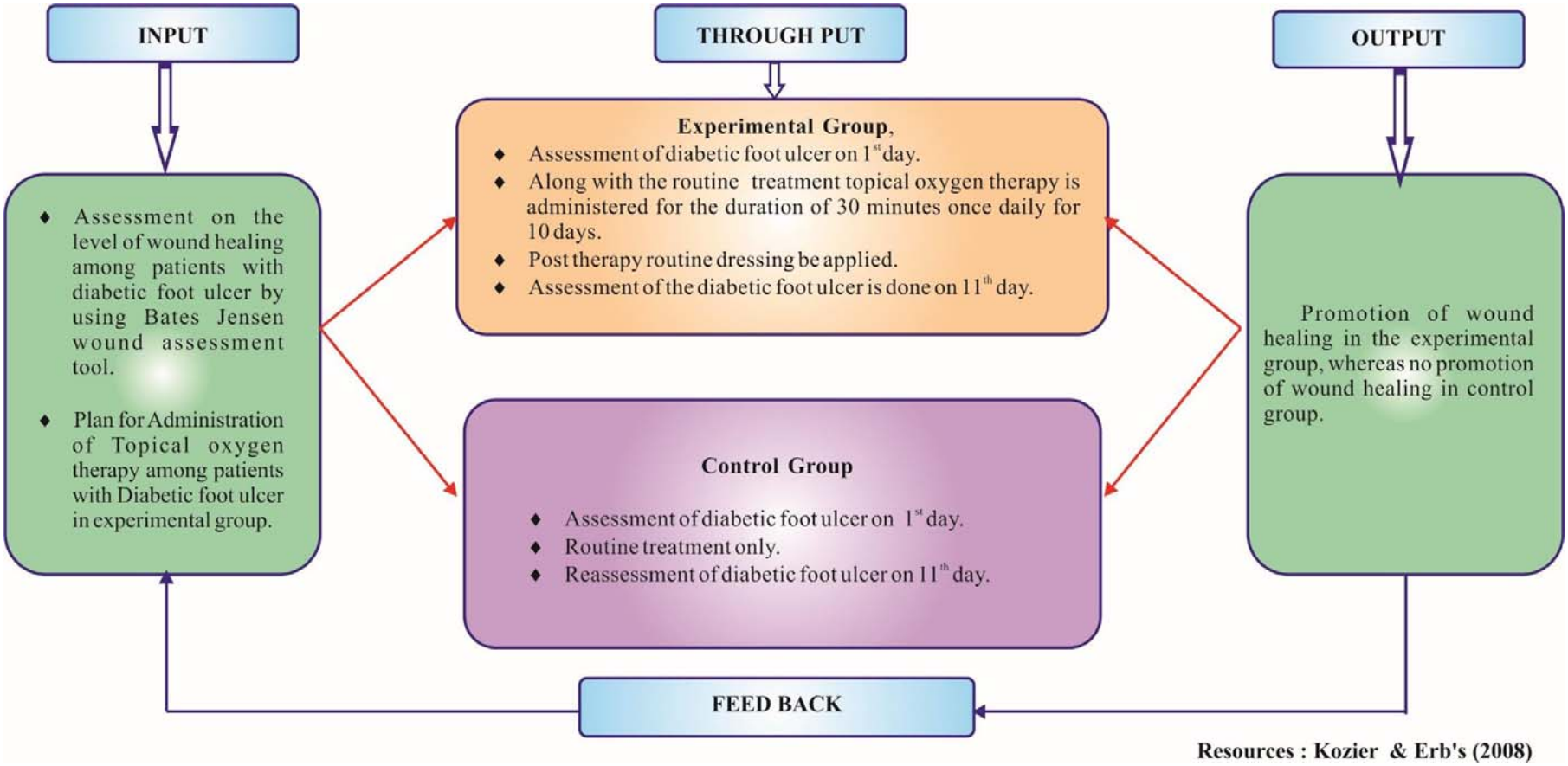
Output

It refers to energy, information or material as a result of throughput. Matter, energy and information are continuously processed through system and released as output in the study. Output expected is faster wound healing which is measured in terms of reduction in the Bates Jensen wound assessment score.

Feedback

It refers to the process by which information is received at each stage of the system and the feedback is given based on the evaluation. In this study it refers to the reduction in the wound status score.

Figure 1.1 : Conceptual Framework Based on General System's Theory by Ludwig Von Bertalanffy (1968)



Resources : Kozier & Erb's (2008)

1.7 Projected Outcome of the Study

Administration of topical oxygen therapy promotes the level of wound healing among patients with diabetic foot ulcer.

LITERATURE REVIEW

Literature is an essential component of the investigator for a greater understanding of the research problem and its major aspects. It provides an opportunity to evaluate many different approaches to the problems. First it is necessary to obtain the most current facts relevant to the problem, and secondly a thorough literature review will assist the selection or development of the theoretical and methodological approaches to the problem.

The literature gathered by the researcher was discussed under the following sections.

2.1. Literature related to diabetic foot ulcer and wound healing

2.2. Literature related to topical oxygen therapy

2.3. Literature related to effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcers.

2.1 LITERATURE RELATED TO DIABETIC FOOT ULCER AND WOUND HEALING

Benjamin & Lipsky (2016) stated that, the major pre disposing factor to these infection is foot ulceration, which is usually related to peripheral neuropathy. Aerobic gram positive cocci (especially staphylococcus aureus) are the pre-dominant pathogens in diabetic foot infections. Patients with chronic wound (or) who have recently received antibiotic therapy may also get infected with gram –negative cocci and those with foot infections(or)gangrene may have aerobic pathogens.

WHO (2015) stated that, diabetes mellitus is a multi-system disease related to abnormal insulin production, impaired insulin utilization (or) both. Diabetes mellitus is a serious health problem throughout the world and is the leading cause of heart disease, stroke, adult blindness and non-traumatic lower limb amputation

Lipsky (2014) retrospectively conducted a study on amputation risk in 3,018 patients hospitalized for a skin (or) soft tissue infection. Analysis of variables like age, gender, serum creatinine, HbA1C, ulcer size, depth, location, periwound edema, foul smelling, presence of exudates, skin temperature, Fever, CRP levels are categorized to mild, moderate, severe. Results showed that patients with periwound edema, presence of exudates found to be associated with amputation.

Lewis (2014) stated that angiopathy (or) blood vessel disease is estimated to account for majority of deaths among patients with diabetes mellitus. These chronic blood vessel dysfunction are divided into two categories. Macrovascular and micro vascular complications.

Edmonds (2014) conducted a cohort study to examine the outcomes in both diabetic neuropathy and ischemic foot. A total of 1232 consecutive individuals presenting with a new diabetic foot ulcer in 14 centers were selected for the study. After 1 year of follow up, 23% of patients wound has not healed .worse healing rates ($P<0.001$) was found in patients with ischemia that of without Ischemia.

Khanolkar (2012) conducted a study on the prevalence of diabetic foot complications. Results showed that diabetic foot ulcer's are frequently more in males and individuals aged over 60 years. The annual population based incidence for diabetic foot ulcer is 1-4% with a prevalence of 4-10%. The lifetime risk was estimated to be 25%.

Edward., et.al (2010) conducted a cohort study to examine the incidence of diabetes related lower extremity complications, among Americans .A total of 1666 patients were evaluated for a period of 24 months. Results showed that, the incidence of ulceration, infection, amputation and lower extremity bypass was 68.4, 36.5,5.9 and 7.7 per 1000 persons with diabetes mellitus each year. The incidence of amputation was high in Mexican Americans than other whites.

Hill (2009) stated that, macro vascular complications are diseases of large and medium blood vessels that occur with greater frequency .Macro vascular disease include cerebrovascular, cardiovascular, peripheral vascular disease (PVD).Although genetic makeup cannot be altered and patient with diabetes can diminish other risk factors associated with microangiopathy such as obesity, smoke, hypertension, high fat diet and sedentary life style.

Hunt(2009) conducted a systematic reviews to prevent foot ulcer amputations in people with diabetes. They conducted this study on 41 samples. They concluded that, effectiveness and safety of following interventions prevent foot ulcers. Interventions include debridement, patients education, pressure of loading with half shoes, screening and referral to foot care clinics, Topical oxygen on infected ulcers, therapeutic footwear and wound dressing.

Gooridge & Donna (2008) stated that, foot ulcer has a major negative effect on health related quality of life. Diabetic foot ulcers have a negative psychological and social effect including reduction to social activities, increased family tension for patients and their care givers, limited employment and financial hardship. Diabetic ulcer exert a negative effect on physical functioning, psychological status and social situation.

Andrew & Boultan (2007) conducted a cohort study on large diabetic subjects(n=9710).The common health setting was followed up to determine the incidence of new foot ulcer. The study reported a 2.2% annual incidence of new diabetic foot ulceration occurs.

Brem.,et.al (2006). Developed a protocol for diabetic foot ulcer for effective management of diabetic foot ulcer. It includes establishment of good communication, among patient and healing team, weekly objective measurement of wound and digital photography, evaluation of blood flow to arteries, use of systemic antibiotics, debridement of hyperkerotic tissue. This study concludes that, availability of above modalities with combination of early recognition and treatment ensures rapid healing and minimize mortality and morbidity.

Ulbrecht (2004) conducted a prevalence study on foot problems in diabetes. Study showed that, diabetes is the leading cause of non-traumatic lower extremity amputations. Most ulcers are neuropathic and plantar in location. When wounds are properly perfused 90% of them heal in 6 weeks. Education should be implemented for all patients with loss of protective sensation

Pecoraro (1990) conducted a cross sectional study to determine the causal pathways responsible for 80 consecutive initial lower extremity. The study was conducted over 30 month interval from 1990-1993. The causal sequences of minor trauma cutaneous ulceration, wound healing failure applied to 72% of the amputations. 59% alleviated to infection, 61% to neuropathy and 81% to faulty wound healing, 40% to ulceration, 55% to gangrene and 81% to initial minor trauma.

Rabkin & Hunt (1988) stated that hypoxic cells are unable to carry out the functions essential to tissue defense and wound healing that any patient who has compromised Pulmonary or cardiovascular functions is at risk for delayed wound healing and wound Infection. This includes patient who are hypovolemic, hypertensive or hypoxic because of trauma, sepsis or impaired cardiac or pulmonary function. Radiation, diabetic angiopathy and peripheral vascular disease can cause enough damage to the capillary basement membrane to severely impair or even prevent wound healing.

Wound healing is a systemic process and is therefore significantly affected by,

Reduced tissue resistance to infection-the ability of leucocytes to kill bacteria is largely oxygen dependent (Frederik 1996).

Tissue perfusion and oxygenation-oxygen fuels the cellular functions essential to the repair process, therefore the ability to perfuse the tissue with adequate amounts of oxygenated blood is critical to wound healing. (Wipke &Stotts 2001)

Tissue hypoxia adversely affects the wound healing in the following ways,

Impaired collagen synthesis- rate of collagen synthesis is dependent on oxygen availability (Martin.,et.al, 2007)

Diabetes mellitus- it has been well established that wound healing is impaired in patients with diabetes mellitus. Studies indicate that patients with diabetes experience reduced collagen synthesis, impaired wound contraction and delayed epidermal migration. (Rosenberg 1990)

Immunosuppression- disease process or medication that suppress the immune system can delay wound healing. This is attributable primarily to impairment of inflammatory process, which increases susceptibility to infection and delays the healing process (Guo 2009)

Other systemic factors-any systemic condition that adversely affects health status can negatively affect wound healing. Renal and hepatic disease, malignancy and sepsis are among these factors. Hematopoietic abnormalities can impair wound healing because red blood cells are needed for oxygen transport and platelets are necessary for hemostasis and for initiation of the wound healing cascade (Lasazarus & cooper 1994).

Wagner (1981) stated that, orthopedic treatment of the dysvascular foot and ankle accounts for 80% of the patients who undergo lower extremity amputation each year. Of those 50-70% are diabetic.

2.2 LITERATURE RELATED TO TOPICAL OXYGEN THERAPY

Hitomi sano (2015) conducted a study to evaluate the effect of topical oxygen therapy for pressure ulcer among bedridden patients. The study consists of 2 samples with a pressure ulcer on the sacrum, II grade pressure ulcer of size 1.5 cm x 1,5 cm. Topical Oxygen therapy was given once per 24 hours with duration of one hour. During the treatment the wound was of scarlet colour and "bloodish". After nine days of treatment the maceration was vanished and the uneven/rough edges of the wound were tidy. The wound showed good granulation tissue after a few days as well as reduction in wound size and depth.

Howard Myles (2014) stated the importance of oxygen in wound healing. It impacts collagen production and development through its effects on enzymes. It has a major role for angiogenesis, the production of granulation tissue and well resistant to infection.

Sen and Gayle (2012) conducted a clinical case series study to evaluate the effect of topical oxygen therapy on chronic wounds. The study was conducted on wounds that failed to heal with standard treatments such as stitches (or) the addition of wound care measures. Topical oxygen therapy was delivered with a inflatable plastic bag with edges that adhered to the skin, secured under affected limb. Treatment duration ranged from 24 days to eight months. Photos were taken before, during, and completion of the therapy. Results showed that wounds closed up to 75 to 100%. Chronic wound showed 92% healing rate.

Chandan (2009) conducted a study on essential of oxygen for wound healing. He reported that, topically applied gas is able to modestly increase the PO_2 levels of the superficial wound tissue. Results from the study demonstrated that, the topical approach to oxygenate the wound significantly enhances the rate of epithelialization of partial thickness wounds and second degree wounds.

Tawfick & Sultan (2009) conducted a parallel observational comparative study included patients who were managed with either topical wound oxygen (n=46) or conventional compression dressings (CCD) (n=37) for 12 weeks or until full healing. At 12 weeks, 80% of topical wound oxygen managed ulcers were completely healed, compared to 35% of CCD ulcers. Median time to full healing was 45 days in topical wound oxygen patients and 182 days in CCD patients. The pain score threshold in topical wound oxygen managed patients improved from8 to 3 by 13 days. After 12-month follow-up, 5 of the 13 healed CCD ulcers showed signs of recurrence compared to none of the 37 topical wound oxygen healed ulcers.

Gordillo.,et al. (2008) studied the results of two simultaneous studies testing the effects of hyperbaric oxygen (HBO) and Topical oxygen therapy(TOT). Patients were screened in outpatient wound clinics for non-randomized enrolments into the HBO (n = 32; 31% diabetic) and TOT (n = 25; 52% diabetic) studies. TOT significantly improved wound size. The investigators concluded that the study provides evidence demonstrating that TOT treatment benefits wound healing in patients suffering from chronic wounds. This study was nonrandomized and not case controlled.

Savitakhana (2006) conducted the study on mode of action of oxygen in promoting wound healing. The researcher said that, oxygen serve as cellular messengers to promote wound healing. The advantages of topical oxygen therapy includes low cost and lack of systemic toxicity

Warriner (2005) According to a position statement for Topical Oxygen for Chronic Wounds, UHMS states that application of topical oxygen cannot be recommended outside of a clinical trial at this time based on the volume and quality of scientific supporting evidence available.

Feldmeier (2005) conducted a prospective study to examine the feasibility of topical oxygen therapy to heal necrotic wounds. Fifteen patients with 24 gangrenous and/or necrotic wounds that did not improve or worsened after at least 6 weeks of standard wound care were treated with topical oxygen therapy by trained HMO personnel. Assessment parameters included wound healing and cost of wound care before and after topical oxygen therapy. 2 wounds healed within 2 to 4 weeks, 3 wounds healed within 4 to 10 weeks and 4 wounds healed within 4 to 12 weeks. The ulcers improved by a mean of 0.829 cm2 per day. 't' test (SSPS 7.5) showed significant improvement per day after topical oxygen therapy, $t = 5.217$, $df = 24$, $P < 0.0001$ (95% CI = 1.13-0.49).

Kranket (2004) stated that, topical oxygen therapy claims several advantages over systemic hyperbaric oxygen therapy including decreased cost, increased safety, decreased complications and putative physiologic effects including decreased free radical formation and more efficient delivery of oxygen to the wound surface .Generally, collagen production and fibroblast proliferation are considered evidence of improved healing in topical oxygen therapy.

Loree (2003) conducted a study to evaluate the effect of oxygen delivery for healing of wounds. The study was conducted over a period of 9 months. 7 surgeons treated 58 wounds. Results showed that, 38 wounds in 15 patients healed on topical oxygen therapy. There was no complication attributable to topical oxygen therapy. The study concluded that, topical oxygen therapy showed beneficial indications for wound healing.

Zipursky.,et.al (1992) conducted a study to find the effect of oxygen therapy on sickle cell disease. 25 patients with sickle cell crisis were choosen randomly to receive either oxygen(n=15 patients) and air(n=10 patients).Those patients who received oxygen showed a significant reduction in reversibility of sickle cells but not in irreversibility of sickle cells.

2.3 LITERATURE RELATED TO EFFECT OF TOPICAL OXYGEN THERAPY ON WOUND HEALING

Brimson & Nigam (2013) conducted a randomized control trial to evaluate the effect of topical Oxygen therapy for reviving the dead wounds. The study consist of 4 patients with diabetic foot ulcer. Topical Oxygen therapy was administered for 2-3 hours per day for 4-5 times per week. Results showed that, topical Oxygen therapy is great potential for wound healing in diabetic patients which has previously failed to progress despite use of aggressive treatments

Blackman.,et.al (2010) conducted a experimental study to evaluate the effect of topical oxygen therapy in treatment of diabetic foot ulcers. The study was conducted in 28 outpatients with severe diabetic foot ulcer. 17 patients were allocated in experimental group and 11 patients were in control group. Patients with diabetic foot ulcer in experimental group received topical oxygen therapy for 5 times in a week for the duration of 30 minutes for 2 weeks. Whereas patients with diabetic foot ulcer in the control group received silver-containing dressing once a day for 2 weeks .The results showed that, 14 out of 17 patients wound scores has reduced from the mean of 84.6 to 46.4 respectively. The “t” value was found to be 12.1which was significant at 0.001 level of significance. Hence topical oxygen therapy is effective in wound healing among patients with diabetic foot ulcer.

David., et.al (2010), developed a model for measuring the transcutaneous penetration of human skin by oxygen. This method was used to determine both the depth and magnitude of penetration of skin by topically applied oxygen. Viable human skin samples of variable thickness with and without epidermis were used

to evaluate the depth and magnitude of oxygen penetration from topical oxygen therapy. Results showed that, topically applied oxygen penetrate through >700 mm of human skin.

Hirsh (2009) conducted a study to evaluate the use of topical oxygen delivery system to promote the healing of chronic lower extremity wound in patients with diabetic foot ulcer. The study consists of 11 patients (5 men and 6 women) with chronic lower extremity wounds unresponsive to previous therapies. Oxygen delivery of 100% oxygen directly to the wound site, which are covered by occlusive dressing. Results showed that, despite chronicity of wound and unresponsive to other therapy5 to 6 wounds had healed after exposure to a period of 2 weeks. The result strongly support the use of oxygen therapy in promoting the healing of diabetic foot ulcers. Amputation was prevented in 2 cases, thus reducing prolonged patient care.

Paola.,et.al (2008) conducted a prospective randomized clinical trial to evaluate the effect of topical Oxygen therapy on wound healing. A total of 22 subjects were participated in the study among which 12 were under experimental group and 10 were in control group. 12 subjects who received topical oxygen therapy was compared with 10 subjects who receive standard of care. Patients were followed up weekly for the assessment of wound characteristics and pictures were taken during each visit. Results showed that after 4 weeks, the percent volume reduction (PVR) was calculated to be 88% for patients who received topical oxygen therapy and 52% for control group. The difference between the two groups was 36% which shows that there is a significant effect in the wound healing process among patients with diabetic foot ulcer.

Donald (2008) conducted a study retrospectively to analyse the efficiency of topical Oxygen therapy in hard to heal diabetic foot ulcers. The study was conducted in an outpatient clinic. 11 patients with an average age of 62.9 years (range 38-93) with 14 Diabetic foot ulcer were included in this evaluation. The average size of ulcers was $5cm^2$ with six ulcers (43%) were on toe, 3 (21%) on plantar surface, 2 (15%) on heel, 2(15%) on the metatarsal area and 1 (7%) on distal leg. After the treatment of 15 days, 12 out of 14 ulcers (86%) healed completely within an average of 46 days. Topical Oxygen therapy as an adjunctive therapy may significantly increase wound healing and re-epithelialization in patients with diabetic foot ulcer.

METHODOLOGY

This chapter deals with the description of research approach, design, setting, population, criteria for sample selection, sampling technique, variables of the study, tools used for data collection, pilot study, procedure for data collection and technique for data analysis.

3.1 Research Approach

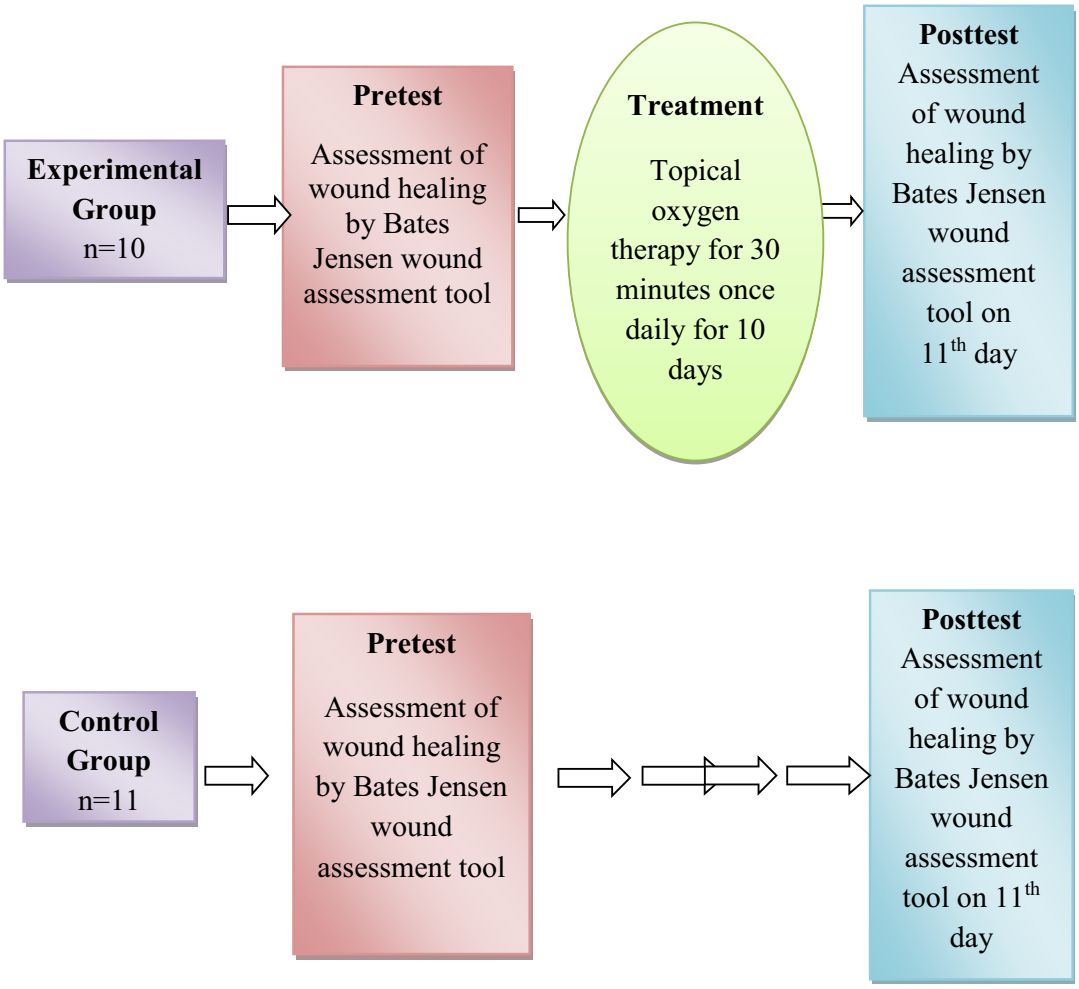
The present study aimed to determine the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer, Here the researcher manipulates the independent variable and measures the change in the dependent variable. Hence, in view of the nature of the problem and to accomplish the objectives, quantitative research approach was adopted for this study.

3.2 Research Design

The research design used for the present study was true experimental design. In this design experimental and control group are selected with randomization (Sharma, 2011). In the present study, participants were distributed to both experimental and control groups randomly. Intervention was given only to the experimental group and the control group was kept under the routine treatment. Hence this design was found to be appropriate to evaluate the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer, at selected hospital, Coimbatore.

Figure 3.1

Diagrammatic Representation of Research Design



3.3 Setting

The study was conducted at selected wards (surgical ward and special wards) of Sri-Ramakrishna hospital located at Siddhapudur, Coimbatore. It is a 700 bedded super speciality hospital under the SNR Sons charitable trust.

3.4 Population

The target population for the present study were patients with diabetic foot ulcer. The accessible populations were patients admitted with diabetic foot ulcer at selected wards of Sri-Ramakrishna hospital, Coimbatore. The annual census of patients admitted with diabetic foot ulcer for the year 2015-2016 was 332. An average of patients admitted were 30 per month. The routine treatment rendered for patients with diabetic foot ulcer includes pharmacological management, wound dressings and wound debridement.

3.5 Sampling

Consecutive sample of 21 hospitalized patients with diabetic foot ulcer were selected for the study. Totally 21 patients were admitted with diabetic foot ulcer during the period of data collection. All the 21 patients who met the sampling criteria were randomly assigned to experimental group (n=10) and control group (n=11) using lottery method.

3.6 Criteria for Sample Selection

3.6.1 Inclusion criteria

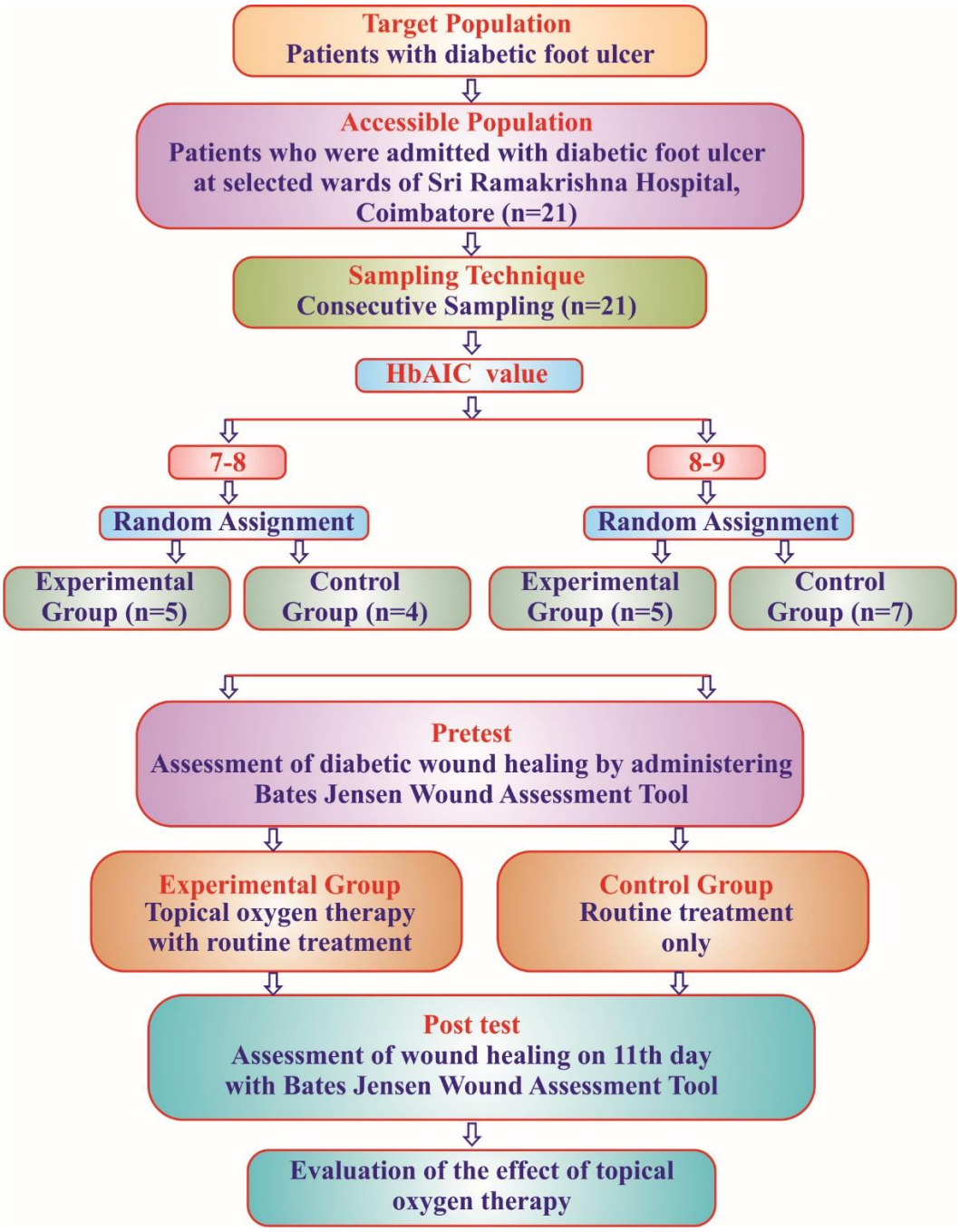
- Patients admitted with new diabetic foot ulcer.
- Patients whose glycosylated haemoglobin value is between 7-9.
- Patients within age group of 45-65 years.
- Patients admitted with type I and Type II diabetes mellitus.

3.6.2 Exclusion criteria

- Patients who are critically ill.
- Patients on corticosteroid therapy.
- Patients with malignancies.
- Patients admitted for surgical wound debridement.
- Patients with non-diabetic foot ulcer.

Figure 3.2

Diagrammatic Representation of Research Process

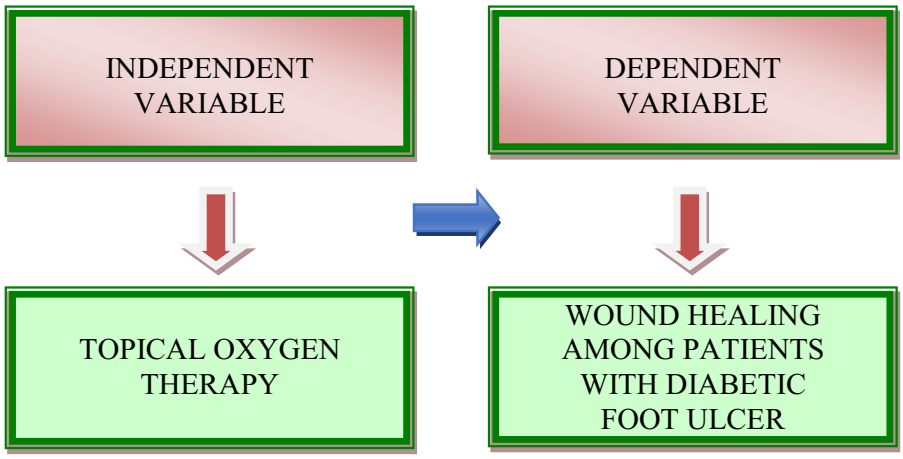


3.7 Variables of the Study

The independent variable of the study was topical oxygen therapy. Dependent variable was wound healing among patients admitted with Diabetic foot ulcer.

Figure 3.3

Schematic Representation of Variables



3.8 Tools for Data Collection

The demographic profile, Bates Jensen wound assessment tool (BWAT) were framed based on the expert opinion and the supportive literatures. The following tools were used for the data collection to assess the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer and it consists of two sections

3.8.1 Demographic profile

3.8.2 Bates Jensen wound assessment tool(BWAT)

3.8.1 Questionnaire on Demographic profile:

Demographic data consists of personal information about the patient such as age, gender, educational status, occupational status, history of smoking, duration of diabetes mellitus, duration of foot ulcer, recent fasting blood sugar value, recent glycosylated haemoglobin value.

3.8.2 The Bates Jensen wound assessment tool (BWAT) 2001:

3.8.2.1 Description of the tool :

Bates Jensen wound assessment tool is a standardized tool developed in the year 1995 by Barbara Bates Jensen and revised in the year 2001.The Bates Jensen wound assessment tool consists of 13 characteristics which assess the wound status in each component .These characteristics include size, depth, edges, undermining, necrotic tissue type, necrotic tissue amount, exudates type, exudates amount, skin colour surrounding tissue, peripheral tissue edema, peripheral tissue induration, granulation tissue and epithelialization.

3.8.2.2 Scoring

Observation technique is used to assess the wound status using a modified Likert scale. Each characteristic can be scored from 1 to 5, with 1 being the best for that attribute and 5 being the worst. After each item is assessed and scored, the 13 subscores are summed to get a total score. The maximum score is 65 indicating wound degeneration and 13 indicates wound regeneration. The total BWAT scores are divided into five severity categories. The higher the total score, the more severe the wound status.

3.8.2.3 Score interpretation:

The scores are interpreted as follows,

13-20	**-**	Wound regeneration
21-30	**-**	Maximum wound healing
31-40	**-**	Moderate wound healing
41-60	**-**	Minimal wound healing
61-65	-	Wound degeneration

3.9 Topical Oxygen Therapy

3.9.1 Description about the therapy

Topical oxygen therapy represents a less explored and less expensive modality in wound healing. Topical oxygen therapies are designed to allow oxygen to enter the wound or skin via the external surface of the body rather than from capillaries within. The oxygen is therefore delivered directly to the wound and the systemic side effects are eliminated.

Topical oxygen therapy is food drug administration(FDA)approved for diabetic ulcers, venous insufficiency, postsurgical infections, gangrenous lesions, pressure ulcers, skin grafts, burns, frostbite, and amputations. It is applied in the comfort of a patient and consists of a sterile, disposable, chamber with adhesive edges applied to the mitten cloth or bag administered around the affected extremity or wound. Treatment includes for the duration of 30 minutes per day for 10 consecutive days and the final re-assessment of the wound was done on the 11^{th} day.

3.9.2 Pre procedure

Explain the needs and usefulness of the therapy to the patient. Explain the procedure. Get informed consent. Maintain good interpersonal relationship. Provide an environment with adequate ventilation. Advice the client to lie down in a comfortable position (supine position)

3.9.3 Procedure

1. Hand washing done
2. After wearing a clean glove the old dressing was removed.
3. Assessment of the diabetic wound was done with Bates Jensen wound assessment tool by assessing the 13 characteristics.
4. The score of day 1 was calculated.
5. The wound was then cleaned with normal saline.
6. The oxygen from central supply was attached to the ethylene oxide(ETO) sterilized extension tube
7. The oxygen carrying tube was attached to the wound and the clean wound was covered with a ETO sterilized mitten cloth and fixed with durapore.
8. Administration of 100%oxygen directly over the wound for 30 minutes once daily.
9. The dressing was assessed in between the therapy to prevent oxygen leak.
10. Post therapy routine dressing was applied to the patient.
11. Assessment of the wound was done on the alternative days before starting the therapy.
12. Final reassessment of the wound status was done on 11^{th} day.

3.10 Validity and Reliability of the Tool:

It refers whether the tool accurately measures what it is supposed to measure. The prepared tool along with the problem statement, objectives, operational definition and hypothesis was validated by five subject experts that included four nursing faculty and one medical expert. The experts were requested to give their opinion and suggestions regarding relevance, appropriateness, accuracy and degree of agreement in each item of the tool. Suggestions and recommendations given by the experts were accepted and necessary corrections were done.

Bates Jensen wound assessment tool is a standardized tool .The reliability score of the tool is r = 0.99 which was found to be significant at 0.001 level .So the tool was found to have high content validity.

3.11 Ethical committee Clearance

After presentation of the proposed tool and data collection procedure approval was obtained from the ethical committee members of the institution.

3.12 Pilot Study

The pilot study was conducted to check the feasibility, practicability, validity of the tool. The study was conducted at selected wards of Sri Ramakrishna Hospital, Coimbatore. The research design used for the present study was quasi experimental with control group design. The sampling technique adopted to recruit the sample was consecutive sampling and 4 patients with diabetic foot ulcer who fulfilled the criteria were recruited in pilot study. The period of data collection was for 10 days. The Bates Jensen wound assessment scale was administered to assess the severity of the wound. The Topical oxygen therapy was administered for the duration of 30 minutes once a day for seven days for each patient. On the eight day, wound was reassessed with the same scale. The

data was tabulated and analyzed using descriptive statistical methods and results showed that the mean score of wound status before and after topical oxygen therapy among experimental group was 51and 15, with the standard deviation of 3 and 1 respectively. The calculated 't' value (18) was more than the table value which was significant at 0.001 level. In the control group the mean scores were48.5 and 46 respectively with a standard deviation of 3.5 and 3.The calculated 't' value was (5.10) which was lesser than the table value. This revealed that the level of wound healing was increased after administration of Topical oxygen therapy. Hence, the study is feasible and practical.

3.12.1 Changes after the pilot study

In order to maintain homogeneity among the samples the researcher decided to have glycosylated haemoglobin as the criteria, to randomize the patients to experimental group and control group. Hence the research design was changed to experimental group design for the main study.

3.13 Procedure for Data Collection

The main study was initiated after the expert guidance and acceptance from the pilot study. The standardized tool was used for data collection and the main study was conducted for a period of 30 days. The study was conducted at selected wards of Sri-Ramakrishna hospital Coimbatore. During the period of data collection, 21 samples were drawn consecutively. Glycosylated haemoglobin value was used to maintain homogeneity among participants and allocated 10 patients into experimental group and 11 patients into control group. The researcher developed rapport with the clients admitted in the ward. Researcher explained about the benefits of the intervention and consent was obtained on the

first day. The intervention was started from the first day. Pretest was done to assess the wound status using Bates Jensen wound assessment tool on both experimental and control group. Then, Topical oxygen therapy was administered to the wound in the experimental group for 30 minutes once daily for a period of 10 days along with the routine care. Control group received only the routine care. Post test was conducted using the same observation tool on the 11th day to evaluate the level of wound healing among patients admitted with Diabetic foot ulcer in both experimental group and control group.

3.14 Techniques of Data Analysis and Interpretation

The frequency tables were formulated for all significant information. Descriptive and inferential statistical method was used for data analysis. Descriptive statistics was applied for the analysis of demographic variables. Inferential statistical methods were used to identify the effect of topical oxygen therapy.

3.14.1 Student 't' test

Student 't' test was used to analyse the effect of topical oxygen therapy on wound healing between experimental group and control group.

$$t = \frac{\overline{X_1} - \overline{X_2}}{SE}$$

Where,

$$SE = SD\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$$

$$SD = \sqrt{\frac{\sum\left(x_1 - \overline{x_1}\right)^2 + \sum\left(x_2 - \overline{x_2}\right)^2}{n_1 + n_2 - 2}}$$

$\overline{X}_1$ = Mean anxiety scores of the experimental group

$\overline{X}_2$ = Mean anxiety scores of the control group

SE = Standard Error

SD = Combined standard deviation

n_1 = Number of samples in experimental group

n_2 = Number of samples in control group

3.14.2 Paired 't' test

Paired 't' test was used to analyse the difference between pre and post test level of wound scores in both groups.

$$t = \frac{\overline{d}}{SE}$$

where,

$$SE = \frac{SD}{\sqrt{n}}$$

$$SD = \sqrt{\frac{\sum D^2 - \frac{\left(\sum D\right)^2}{n}}{n-1}}$$

$\overline{d}$ = Mean of difference between test score

SE = Standard Error

SD = Standard deviation of the test score

n = Number of samples

3.14.3 Chi-Square test (with yates correction)

Chi-Square (with yates correction) test was used to check the association between the pretest level of wound healing and selected demographic variables.

$$\chi^2 = \sum \frac{\left((O-E)-0.5\right)^2}{E}$$

O = Observed value

E = Expected value in corresponding category

0.5 = Yates correction value

DATA ANALYSIS AND INTERPRETATION

Chapter IV deals with the analysis and results of data collected from 21 patients with diabetic foot ulcer. The aim of the study was to determine the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer. Total number of 21 patients who met the criteria were selected using consecutive sampling technique for the study. Among 21 samples, 10 patients were recruited randomly to experimental group and 11 patients to control group respectively. The intervention selected for the study was topical oxygen therapy. The level of wound healing among patients with diabetic foot ulcer was assessed with Bates Jensen wound assessment tool before and after the intervention.

Descriptive and inferential statistics were employed to analyze the data. Frequency and percentage were used to present the demographic characteristics and the level of wound healing was analyzed through mean, standard deviation and mean difference. Paired‘t’ test was used to analyze the difference between pre and post test level of wound healing in both groups respectively. Student ‘t’ test was used to analyze the effect of topical oxygen therapy on level of wound healing among experimental and control group. Chi square test was used to analyze the association between pre-test level of wound healing and selected demographic variables.

ORGANIZATION OF THE FINDINGS

The data obtained from patients with diabetic foot ulcer are organized, analyzed and presented under the following sections.

Section I

Demographic Variables of patients with diabetic foot ulcer.

Section II

Level of wound healing among experimental group and control group before topical oxygen therapy.

Section III

Level of wound healing among experimental group and control group after topical oxygen therapy.

Section IV

Comparison on level of wound healing among experimental groupand control group before and after topical oxygen therapy.

Section V

Effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer.

Section VI

Association between the pretest level of wound healing and selected demographic variables among patients with diabetic foot ulcer.

Section I

Demographic variables of Patients Admitted with Diabetic Foot Ulcer

Demographic variables such as age, gender, education, occupation, history of smoking, duration of diabetes mellitus, duration of foot ulcer, recent FBS value, recent glycosylated hemoglobin were analyzed using descriptive statistics in terms of frequency and percentage. Analysed data were presented in the form of tables and diagrams.

Table 4.1.1

Age of patients with diabetic foot ulcer

(n=21)

S. No	Age (years)	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	45-50	1	10	2	18.18
2.	51-55	2	20	4	36.36
3.	56-60	4	40	3	27.28
4.	61-65	3	30	2	18.18

The above table 4.1 depicts that, in the experimental group majority of 4(40%) patients belong to the age group of 56-60 years, 3(30%) patient between 61-65 years, 2(20%)patient between 51-55 years,1(10%) patient belong to age group of 45-50 years. In the control group 4(36.37%) patients belong to age group of 51-55 years.

Table 4.1.2

Gender of patients with diabetic foot ulcer

(n=21)

S.No	Gender	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	Male	10	100	8	72.73
2.	Female	-	-	3	27.27

The above table 4.1.2 depicts that in the experimental group all were males (100%) and in the control group 8 (72.73%) were males and 3(27.27%) were females.

Figure 4.1.1

Age of patients with diabetic foot ulcer

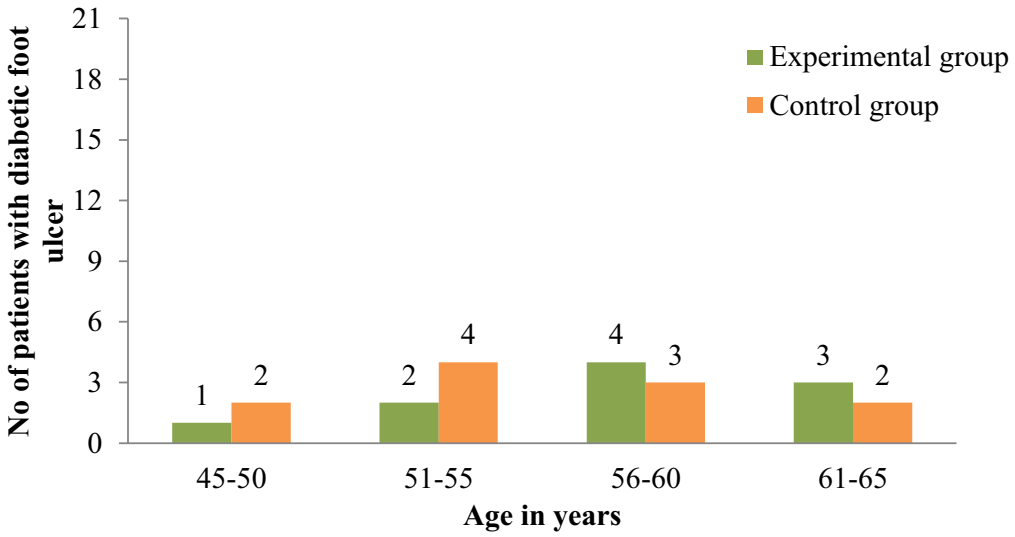


Figure 4.1.2

Gender of patients with diabetic foot ulcer

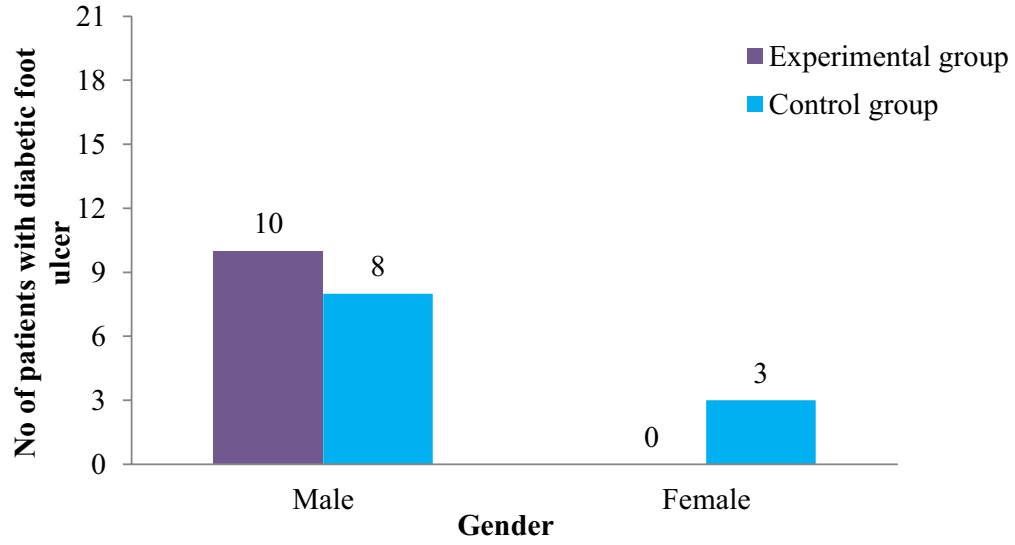


Table 4.1.3

Educational Status of patients with diabetic foot ulcer

(n=21)

S.No	Educational status	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	Illiterate	-	-	1	9.09
2.	Primary education	3	30	2	18.18
3.	Secondary education	1	10	3	27.28
4.	Higher secondary education	4	40	4	36.36
5.	Graduate	2	20	1	9.09

The above table 4.1..3 depicts that majority of 4(40%) patients had higher secondary education, 3(30%) patients had primary education and 2(20%) were graduates. In control group majority of 4(36.36%)patients had higher secondary education,3(27.28%)patients completed their higher secondary education.

Table 4.1.4

Occupational Status of patients with diabetic foot ulcer

(n=21)

S. No	Occupational status	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	Coolie worker	4	40	2	18.18
2.	Private employee	1	10	3	27.27
3.	Govt employee	2	20	2	18.18
4.	Unemployed	3	30	4	36.37

The above table 4.1.4 depicts that in experimental group 4(40%) patients were coolie workers, 3(30%) patients were unemployed, 2(20%) patients were government employees and 1(10%) was a private employee. In control group 4(36.37%) patients were unemployed,3 (27.28%) patients were private employees, 2(18.19%) were coolie workers and 2(18.19%) were Govt employee respectively.

Figure 4.1.3

Educational Status of patients with diabetic foot ulcer

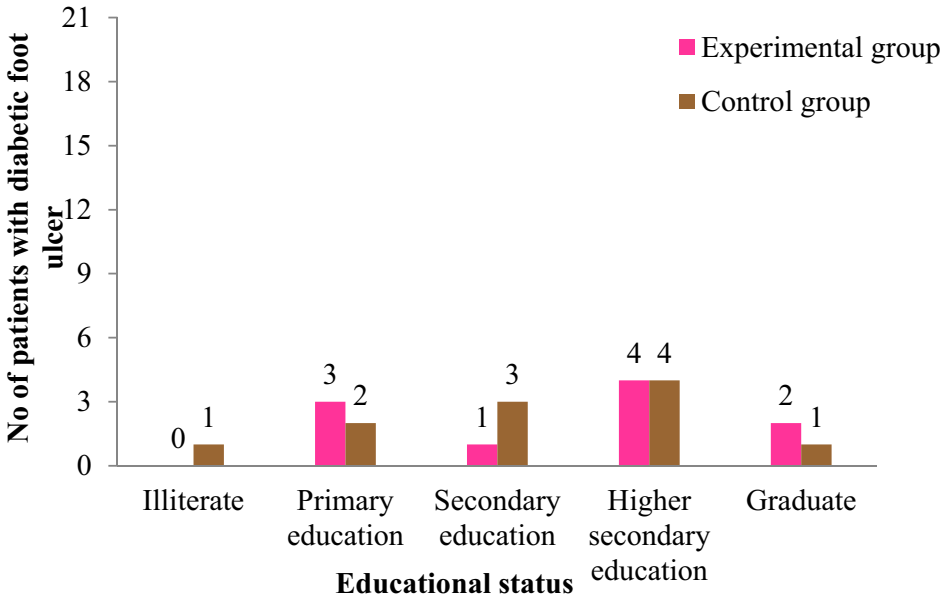


Figure 4.1.4

Occupational Status of patients with diabetic foot ulcer

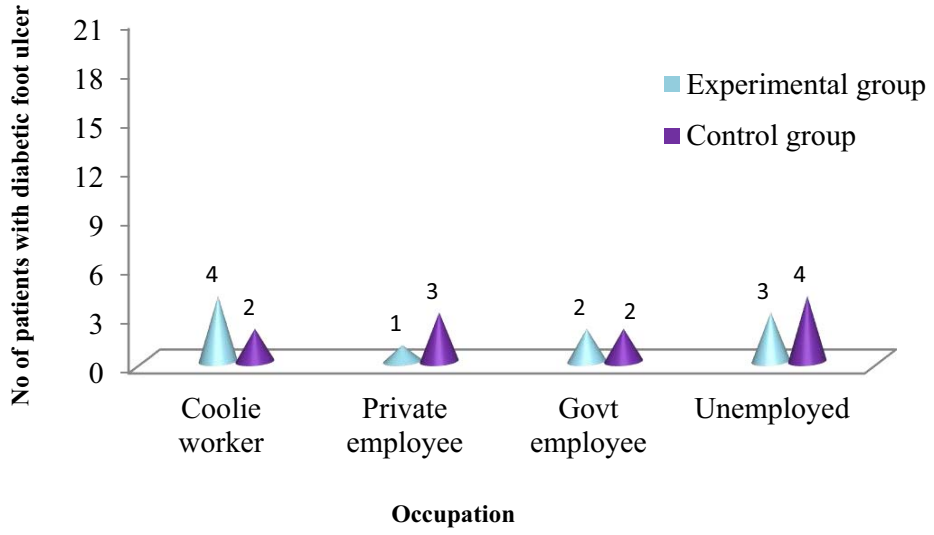


Table 4.1.5
History of Smoking of patients with diabetic foot ulcer

(n=21)

S.No	History of smoking	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	Yes	6	60	7	63.64
2.	No	4	40	4	36.36

Patients with diabetic foot ulcer based on smoking shows that, in experimental group 6 (60%) patients were smokers and 4 (40%) patients were non-smokers. In control group 7(63.64%) patients were smokers and 4 (36.36%) patients were non-smokers.

Table 4.1.6
Duration of Diabetes Mellitus of Patients with diabetic foot ulcer

(n=21)

S.No	Duration of Diabetes Mellitus	Experimental group(n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	4-6 years	3	30	2	18.18
2.	7-9 years	4	40	5	45.45
3.	10-13years	3	30	4	36.37

Table 4.1.6 depicts the patients with diabetic foot ulcer and duration of diabetes mellitus showed that 3 (30%) patients had diabetes mellitus between 4-6 years, 4 (40%) patients had between 7-9 years and 3(30%) patients for more than 10 years. In control group majority of 5(45.46%) patients had diabetes mellitus between 7-9 years.

Figure 4.1.5

History of Smoking of patients with diabetic foot ulcer

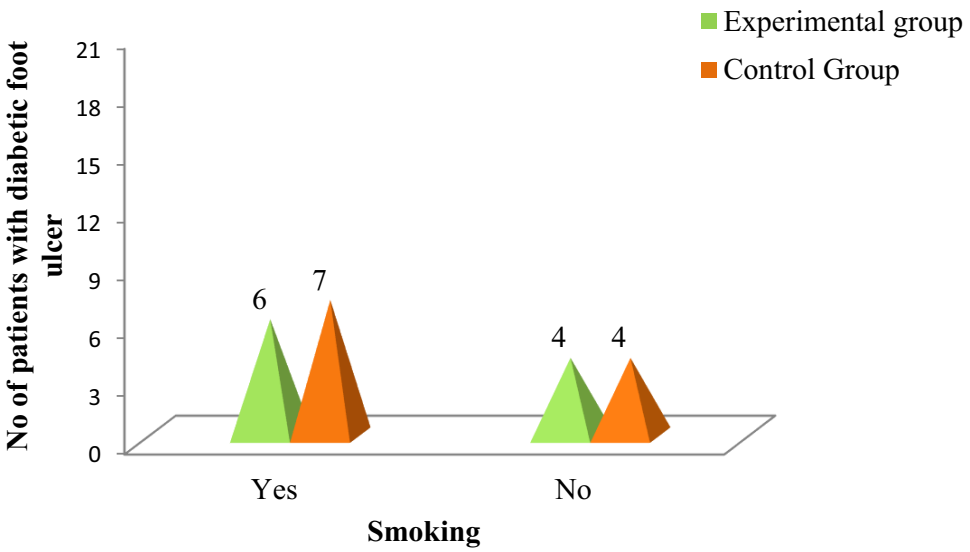


Figure 4.1.6

Duration of Diabetes Mellitus of Patients with diabetic foot ulcer

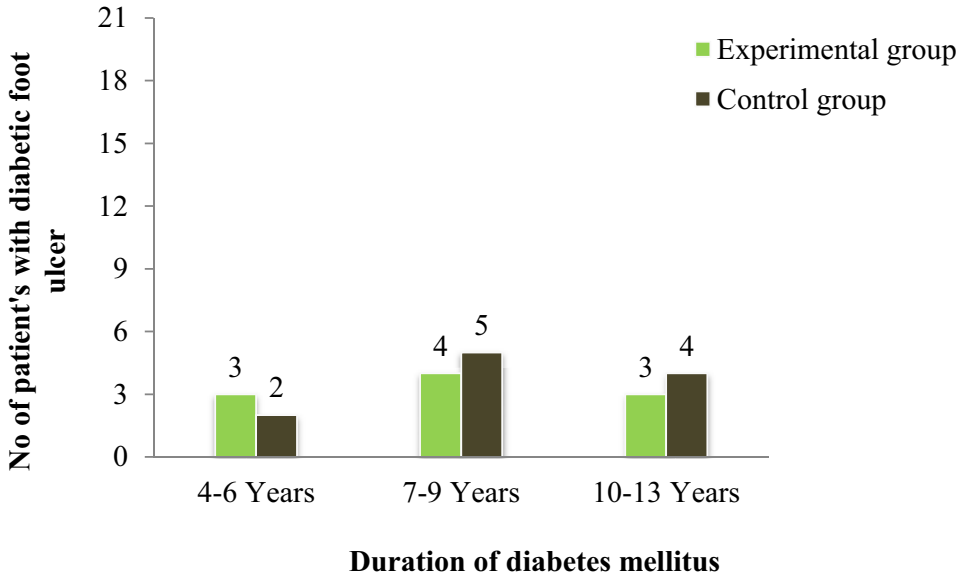


Table 4.1.7

Duration of foot ulcer of patients with diabetic foot ulcer

(n =21)

S.No	Duration of Foot Ulcer	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	0-1 month	1	10	2	18.18
2.	1-2 months	1	10	2	18.18
3.	2 -3months	3	30	3	27.28
4.	3-4 months	5	50	4	36.36

Table 4.1.7 depicts the distribution of patients by duration of foot ulcer. The result shows that in experimental group, majority 5(50%) patients had foot ulcer, 3(30%) patients had between 3-4 months. In control group 4(36.36%) patients had foot ulcer between 3-4 months, 3(27.28%) patients had foot ulcer between 2-3 months.

Table 4.1.8

Recent fasting blood sugar value of patients with diabetic foot ulcer

(n=21)

S.No	Recent FBS value (mg/dl)	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	80-120	2	20	4	36.36
2.	121-160	6	60	5	45.46
3.	161-200	2	20	2	18.18

Table 4.1.8 depicts that distribution of patients with recent FBS value shows in experimental group 6(60%) patients had FBS between 121-160mg/dl ,2(20%) patients between 80-120mg/dl and 2(20%)between 161-200mg/dl. In control group 5(45.46%) patients had FBS between 121-160 mg/dl, 4(36.36%) had between 80-120 mg/dl and 2(18.181) between 161-200mg/dl.

Figure 4.1.7

Duration of foot ulcer of patients with diabetic foot ulcer

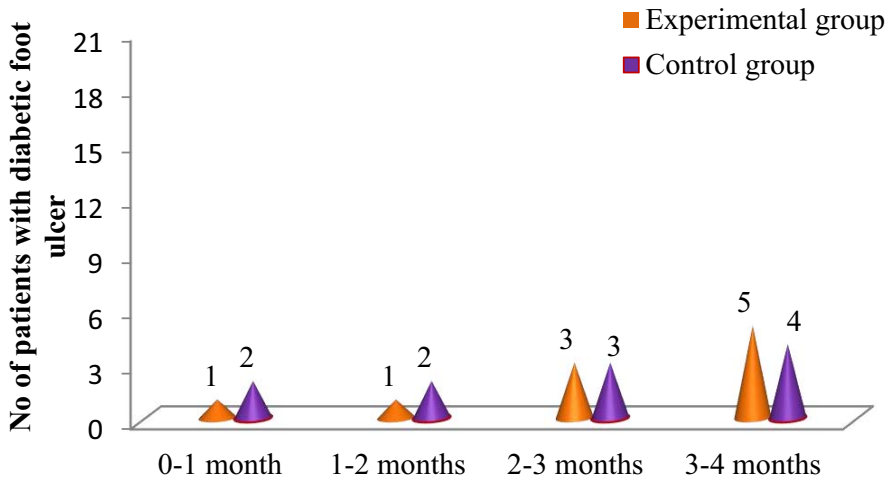


Figure 4.1.8

Recent fasting blood sugar value of patients with diabetic foot ulcer

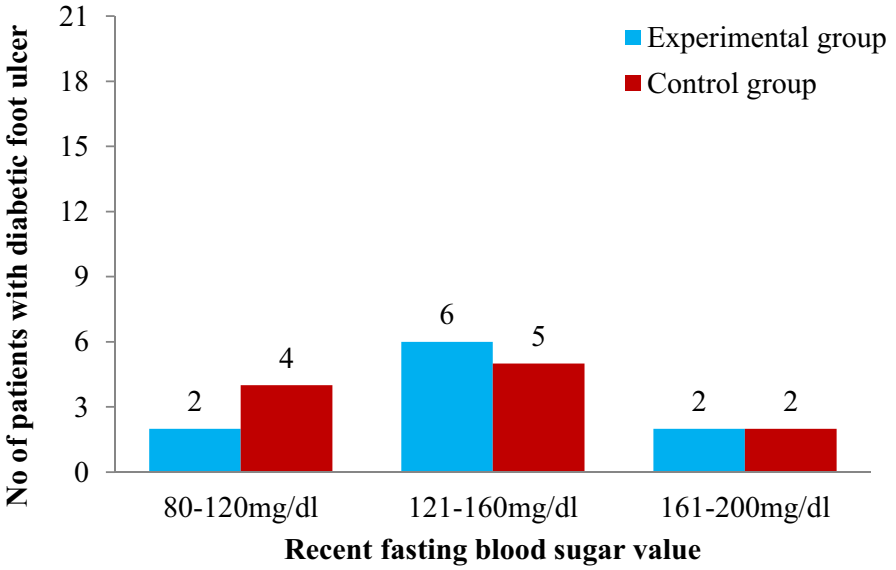


Table 4.1.9

Glycosylated hemoglobin value of patients with diabetic foot ulcer

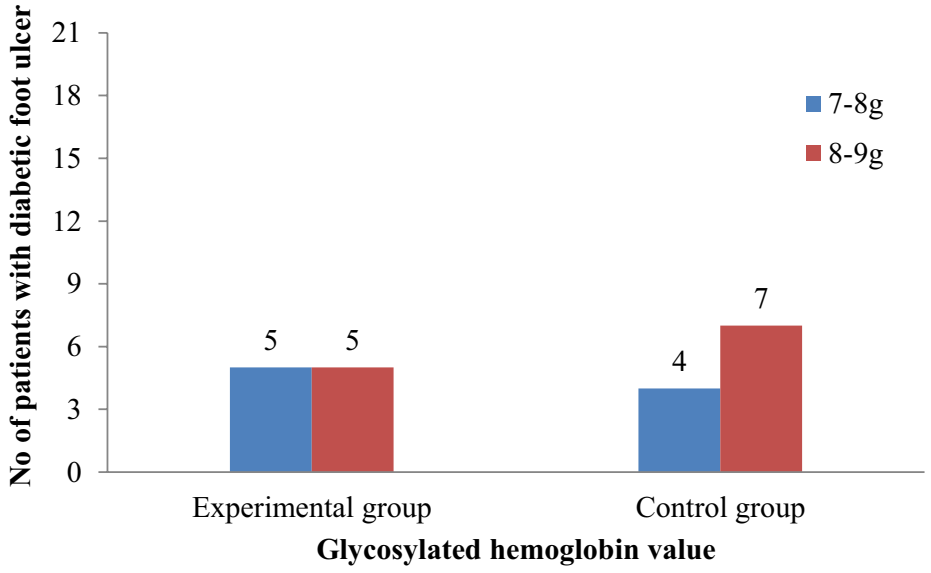
(n=21)

S.No	Glycosylated hemoglobin value	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	7-8	5	50	4	36.37
2.	8-9	5	50	7	63.63

Table 4.1.9 depicts no of patients with diabetic foot ulcer on recent glycosylated hemoglobin value shows 5(50%)patients had value between 7-8 and5(50%) had more than 8 in experimental group. In control group 4(36.36%) patients had between 7-8 and 7(63.63 %) patients had more than 8.

Figure 4.1.9

Glycosylated hemoglobin value of patients with diabetic foot ulcer



Section II

Level of wound healing among experimental and control group before topical oxygen therapy

This section deals with the level of wound healing among patients with diabetic foot ulcer before topical oxygen therapy, which was assessed using Bates Jensen wound assessment tool. The level of wound healing was categorized as wound regeneration, maximum wound healing, moderate wound healing, minimal wound healing and wound degeneration. Collected data were organized, analyzed and presented using descriptive statistics.

Table 4.2.1

Level of wound healing among experimental group and control group before topical oxygen therapy

(n=21)

S.No	Level of Wound healing	Experimental group (n= 10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	Wound regeneration	-	-	1	9.09
2.	Maximum wound healing	2	20	2	18.18
3.	Moderate wound healing	5	50	6	64.55
4.	Minimal wound healing	2	20	2	18.18
5.	Wound degeneration	1	10	-	-

The above table 4.2.1 shows the number of patients with diabetic foot ulcer based on the level of wound healing before Topical Oxygen therapy in experimental and control group. It was found that 5(50%) patients had moderate wound healing, 2(20%) patients had maximum wound healing, 2(20%)patients had minimal wound healing and 1(10%)patient had wound degeneration(Figure 4.2.1).In control group, majority of 6(54.55%) patients had moderate wound healing,2(18.18%) patients had maximum wound healing, ,2(18.18%) patients had minimum wound healing.

Figure 4.2.1

Level of wound healing among experimental group and control group

Before topical oxygen therapy

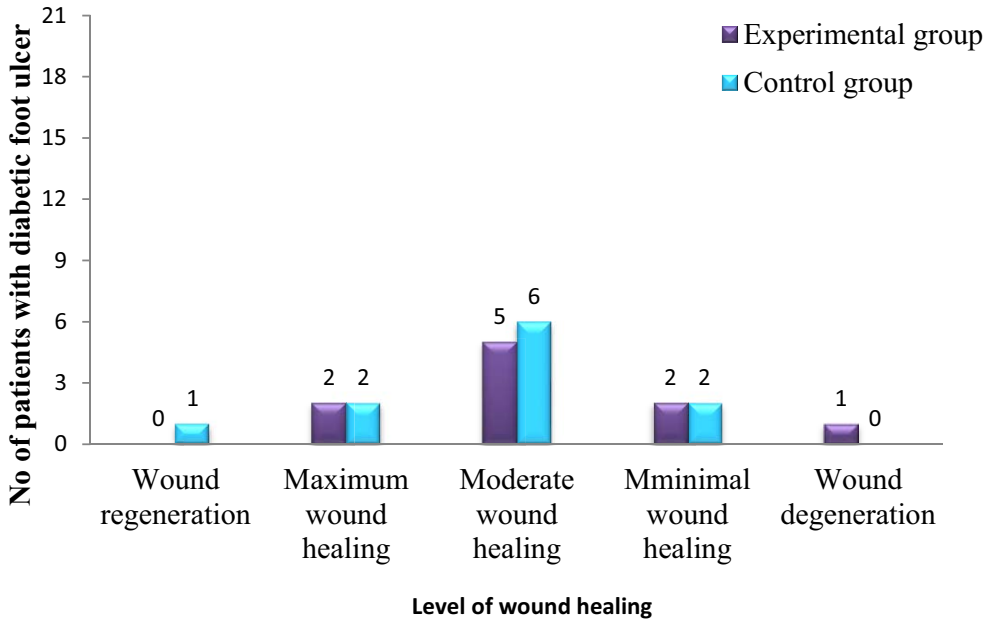


Table 4.2.2

Wound healing scores among experimental group and control group before topical oxygen therapy

(n=21)

S.No	Wound Healing Scores	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	13-18	-	-	-	-
2.	19-24	1	10	1	9.08
3.	25-30	1	10	2	18.18
4.	31-36	2	20	3	27.28
5.	37-42	3	30	3	27.28
6.	43-48	2	20	-	-
7.	49-54	-	-	2	18.18
8.	55-60	-	-	-	-
9.	61-65	1	10	-	-

The above table 4.2.2 depicts the wound healing scores obtained by the patients with diabetic foot ulcer before topical oxygen therapy in both experimental and control group. The result shows that in experimental group, 3 (30%) patients scored between37-42, 4 (40%) patients scored between 43-48 and 31-36 respectively. In control group 3(27.28%) patients scored between 37-42 and 3(27.28%) patients scored between 31-36.

Section III

Level of wound healing among experimental and control group after topical oxygen therapy

This section deals the level of wound healing among patients with diabetic foot ulcer after topical oxygen therapy, which was assessed by using Bates Jensen wound assessment tool. The level of wound healing was categorized as wound regeneration, maximum wound healing, moderate wound healing, minimal wound healing and wound degeneration. Collected data were organized, analyzed and presented by using descriptive statistics.

Table 4.3.1
Level of wound healing among experimental group and control group after topical oxygen therapy

(n=21)

S.No	Level of wound healing	Experimental group (n= 10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1	Wound regeneration	4	40	-	-
2	Maximum wound healing	4	40	3	27.28
3	Moderate wound healing	2	20	4	36.36
4	Minimum wound healing	-	-	4	36.36
5	Wound degeneration	-	-	-	-

The above table 4.3.1 shows number of patients with diabetic foot ulcer based on the level of wound healing after topical oxygen therapy. It was found that 4(40%) patients had maximum wound healing and 4(40%)patients had wound regeneration and 2(20%)patients had moderate wound healing in Experimental group(Figure 4.3.1). Among the control group 3 (27.28%) patients had maximum wound healing 4 (36.36%) patients had moderate wound healing and 4(36.36%) patients had minimum wound healing.

Figure 4.3.1

Level of wound healing among experimental group and control group after topical oxygen therapy

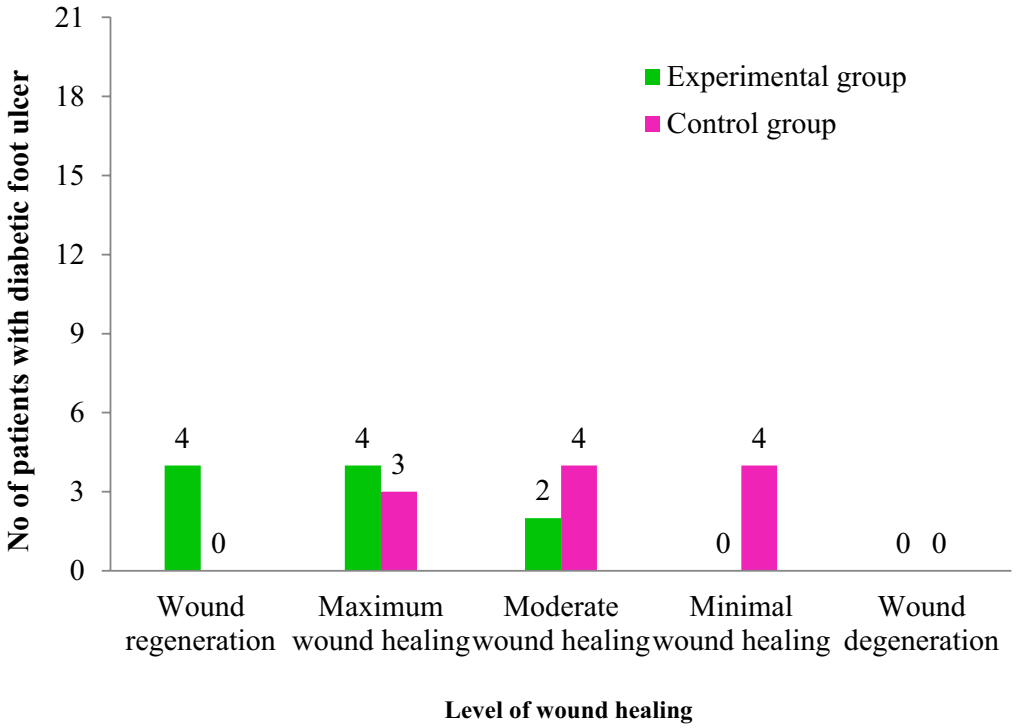


Table 4.3.2

Wound healing scores among experimental and control group after topical oxygen therapy

(n=21)

S.No	Wound Healing Scores	Experimental group (n=10)		Control group (n=11)	
		Frequency	Percentage (%)	Frequency	Percentage (%)
1.	13-18	2	20	-	-
2.	19-24	4	40	-	-
3.	25-30	2	20	3	27.27
4.	31-36	1	10	2	18.19
5.	37-42	1	10	3	27.27
6.	43-48	-	-	1	9.09
7.	49-54	-	-	1	9.09
8.	55-60	-	-	1	9.09
9.	61-65	-	-	-	-

The above table 4.3.2 depicts the wound healing scores obtained by the patients with Diabetic foot ulcer after Topical Oxygen therapy in both experimental and control group. The result shows that in experimental group majority of 4(40%) patients had wound healing scores between 19-24, whereas in the control group 3(27.27%) patients had wound healing scores between 25-30 and 3(27.27%) patients had wound healing scores between 37-42 respectively.

Section IV

Table 4.4.1

Comparison on level of wound healing among experimental group and control group before and after topical oxygen therapy

(n=21)

S.No	Level of wound healing	Experimental group (n=10)				Control group (n=11)			
		Pretest		Post test		Pretest		Post test	
		Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)
1	Wound regeneration	-	-	4	40	1	9.09	-	-
2	Maximum wound healing	2	20	4	40	2	18.18	3	27.28
3	Moderate wound healing	5	50	2	20	6	64.55	4	36.36
4.	Minimal wound healing	2	20	-	-	2	18.18	4	36.36
5.	Wound degeneration	1	10	-	-	-	-	-	-

Before intervention it was found that, 5 (50%) patients with diabetic foot ulcer from experimental group had moderate wound healing, 2(20%) patients had maximum wound healing, 2(20%) patients had minimal wound healing and 1(10%) patient had wound degeneration. Whereas after intervention, it was identified that 4(40%) patients had wound regeneration, 4(40%) patients had maximum wound healing and 2 (20%) patients had moderate wound healing. In the experimental group the mean wound healing score was reduced from 38.9 to 24.8 respectively.

In control group, pretest level showed that majority of 6(54.55%) patients with diabetic foot ulcer had moderate wound healing, and posttest level showed that, 4 (36.36%) patients had moderate level wound healing ,4(36.36%) patients had minimal wound healing ,3(18.18%) patients had maximum level of wound healing. In control group the mean wound healing score was increased from 36.6 to 38.9 respectively.

Figure 4.4.1

Comparison on level of wound healing among experimental and control group before and after topical oxygen therapy

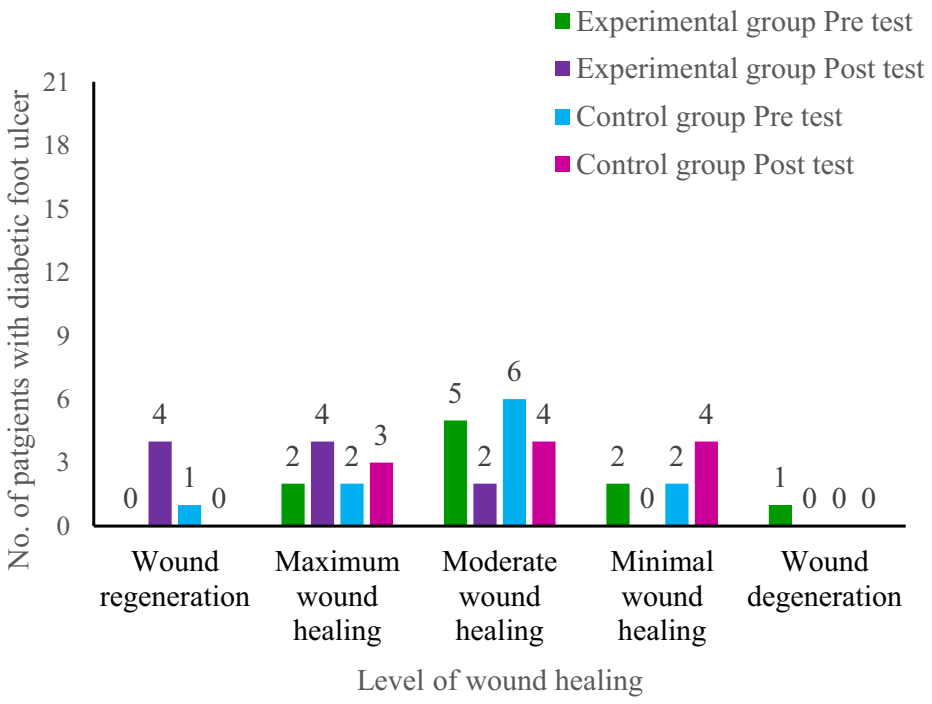


Table 4.4.2

Comparison on wound healing scores among experimental group and control group before and after topical oxygen therapy

(n=21)

S.No.	Wound healing Score	Experimental group (n=10)				Control group (n=11)			
		Pre test		Post test		Pretest		Post test	
		Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)	Frequency	Percentage (%)
1.	13-18	-	-	2	20	-	-	-	-
2.	19-24	1	10	4	40	1	9.08	-	-
3.	25-30	1	10	2	20	2	18.18	3	27.27
4.	31-36	2	20	1	10	3	27.28	2	18.19
5.	37-42	3	30	1	10	3	27.28	3	27.27
6.	43-48	2	20	-	-	-	-	1	9.09
7.	49-54	-	-	-	-	2	18.18	1	9.09
8.	55-60	-	-	-	-	-	-	1	9.09
9.	61-65	1	10	-	-	-	-	-	-

During pretest in experimental group, 3(30%) patients scored between 37-42 and 2(20%) patients scored between 31-36 and 2(20%) patients scored between 31-48 respectively. After topical oxygen therapy, it was found that none of the patient had scored above 43 and 4(40%) patients scored between 19-24,2(20%) patients scored between 13-18 and 2(20%) patients scored between 25-30.

In control group, on pretest there were 3(27.28%) patients who scored between 31-36,3 (27.28%)patients scored between 37-42. whereas in the post test, 3 (27.28%)patients scored above 45.

Section V

Effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer

This section deals with the analysis and interpretation of the effect of topical oxygen therapy among patients with diabetic foot ulcer. Analyzed data were presented on the following headings.

1. Assessment on wound healing among experimental group and control group before topical oxygen therapy.
2. Assessment on wound healing among patients with diabetic foot ulcer in experimental group.
3. Assessment on wound healing among patients with diabetic foot ulcer in control group.
4. Effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer.

Table 4.5.1

Assessment on level of wound healing among experimental and control group before topical oxygen therapy

(n=21)

Group	Mean	SD	Mean difference	't' value
Experimental Group	38.9	9.92	2.3	0.53
Control Group	36.6	8.81		

Student ‘t’ test was used to assess the level of wound healing before Topical Oxygen therapy among both the groups. It was identified that the mean level of wound healing among patients with diabetic foot ulcer in experimental and control group was 38.9 and 36.6 respectively with a mean difference of 2.3 Likewise the standard deviation of the experimental and control group was 9.92 and 8.81 respectively. The calculated ‘t’ value was 0.53 which was less than the table value.

Table 4.5.2

Assessment on level of wound healing among patients with diabetic foot ulcer in experimental group

(n=10)

Level of wound healing	Mean	SD	Mean difference	't' value
Before intervention	38.9	9.92	14.1	7.29***
After intervention	24.8	10.82		

***Significant at 0.001 level

Paired‘t’ test was used to assess the level of wound healing among patients with diabetic foot ulcer before and after the intervention. It was identified that, the mean score before and after topical oxygen therapy among experimental group was 38.9 and 24.8 respectively with a mean difference of 14.1. Standard deviation was 9.92 and 10.82. The calculated ‘t’ value was 7.29. While comparing with table value, it showed that the calculated ‘t’ value was greater than the table value at 0.001 level of significance. Hence a highly significant difference was found in the level of wound healing among patients with diabetic foot ulcer in experimental group before and after implementation of topical oxygen therapy.

Table 4.5.3

Assessment on level of wound healing among patients with diabetic foot ulcer in control group

(n=11)

Level of wound healing	Mean	SD	Mean difference	't' value
Pre test	36.6	8.81	2.3	1.35
Post test	38.9	10.31		

Paired ‘t’ test was used to assess the pretest and post test level of wound healing among patients with diabetic foot ulcer in control group. It was identified that, the mean pretest and post test wound healing score was 36.6 and 38.9 respectively with a mean difference of 2.3. Standard deviation was 8.81 and 10.31 respectively and the calculated ‘t’ value was 1.35 which was lesser than the table value. Hence significant difference was not found in the pretest and post test level of wound healing among patients with diabetic foot ulcer in control group.

Table 4.5.4

Effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer

(n=21)

Group	Mean	SD	Mean difference	't' value
Experimental Group	24.8	7.42	14.1	3.40**
Control Group	38.9	10.31		

**Significant at 0.01 level

Un paired 't' test was used to compare the post test level of wound healing among experimental and control group. It was identified that the mean level of wound healing among patients with diabetic foot ulcer in experimental and control group was 24.8 and 38.9 respectively with a mean difference of 14.1. Likewise the standard deviation of the experimental and control group was 7.42 and 10.31 respectively. The calculated 't' value was 3.40 which was greater than the table value at 0.01 level of significance. Hence the research hypothesis 'There will be a significant difference in the level of wound healing among experimental group and control group after administration of topical oxygen therapy among patients with diabetic foot ulcer was accepted'.

Section VI

4.5 Association between the Pretest Level of wound healing and selected demographic variables among patients with diabetic foot ulcer

Chi square test (with Yates correction) was used to find the association between level of wound status and selected demographic variables like age, gender, education, occupation, history of smoking, duration of diabetes mellitus, duration of foot ulcer, recent fasting blood sugar value, recent glycosylated hemoglobin value among patients with diabetic foot ulcer.

Table 4.6.1

Association between the pretest level of wound healing and selected demographic variables among patients with diabetic foot ulcer

(n=21)

S.No	Demographic variables	Category	Frequency	Level of wound healing				χ^2 value (Yates correction)	Degree of freedom (r-1)(c-1)	χ^2Table value
				Wound regeneration	Maximum wound healing	Moderate wound healing	Minimal wound healing	Wound degeneration			
1.	Age	45-50 years	3	1	1	1	0	0	21.20*	12	18.55
		51-55 years	6	0	1	3	2	0			
		56-60 years	7	0	2	4	1	0			
		61-65 years	5	0	0	3	1	1			
2.	Sex	Male	18	1	4	9	3	1	8.49	4	9.49
		Female	3	0	0	2	1	0			
3.	Educational status	Illiterate	1	0	1	0	0	0	42.07*	16	26.30
		Primary	5	1	1	3	0	0			
		Secondary	4	0	1	2	1	0			
		Higher secondary	8	0	1	5	1	1			
		Graduate	3	0	0	1	2	0			

S.No	Demographic variables	Category	Frequency	Level of wound healing					χ^2 value (Yates correction)	Degree of freedom (r-1) (c-1)	χ^2 Table Value
				Wound regeneration	Maximum wound healing	Moderate wound healing	Minimal wound healing	Wound degeneration			
4.	Occupation	Coolie	6	1	3	2	0	0	27.72*	12	21.03
		Private	4	0	1	2	1	0			
		Government	4	0	0	1	2	1			
		unemployed	7	0	0	6	1	0			
5.	History of smoking	Yes	13	1	3	7	2	0	6.21	4	9.49
		No	8	0	1	4	2	1			
6.	Duration of diabetes mellitus	4-6 year	5	0	0	3	2	0	16.03*	8	15.51
		7-9 years	9	1	3	3	2	0			
		10-13 years	7	0	1	5	0	1			

S.No	Demographic variables	Category	Frequency	Level of wound healing					χ^2 value (Yates correction)	Degree of freedom (r-1) (c-1)	χ^2 Table Value
				Wound regeneration	Maximum wound healing	Moderate wound healing	Minimal wound healing	Wound degeneration			
7.	Duration of foot ulcer	0-1 month	3	0	1	2	0	0	24.67*	12	21.03
		1-2 month	3	0	0	1	2	0			
		2-3 month	6	0	2	3	1	0			
		3-4 month	9	1	1	5	1	1			
8.	Recent FBS value	80-120mg/dl	6	0	1	4	1	0	12.79	8	15.51
		121-160mg/dl	11	1	3	5	2	0			
		161-200mg/dl	4	0	0	2	1	1			
9.	Glycosylated HB value	7-8	9	0	2	6	0	1	7.46	4	9.49
		8-9	12	1	2	6	3	0			

Significance at 0.05 level

Table 4.6.1 shows the association between pretest level of wound healing and selected demographic variables among patients with diabetic foot ulcer. selected demographic variables were like age, gender, education, occupation, history of smoking, duration of diabetes mellitus, duration of foot ulcer, recent fasting blood sugar value, recent glycosylated hemoglobin value among patients with diabetic foot ulcer.

It was found that chi square value for age (χ^2=21.20), occupational status (χ^2=27.72), educational status (χ^2=42.07), duration of diabetes mellitus (χ^2=16.03), duration of foot ulcer (χ^2=24.67) had association with the level of wound status among patients with diabetic foot ulcer at 0.05 level of significance. History of smoking (χ^2=6.21), recent FBS value (χ^2=12.79), glycosylated HB (χ^2=7.46) had no association with the level of wound healing among patients with diabetic foot ulcer.

RESULTS AND DISCUSSION

This chapter deals with the interpretation of the results and discussion of the findings. The main aim of the study was to assess the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer. True experimental randomized control group design was adopted in this study. In the present study, 21 samples were selected by convenient sampling technique. The samples were randomly assigned to experimental group (n=10) and control group (n=11). Topical oxygen therapy was administered to the experimental group for a period of 30 minutes for 10 days. The level of wound healing was assessed before and after the intervention. The data were analyzed and the findings are discussed based on the objectives of the study.

5.1 Findings related to demographic profile

The age of patients with diabetic foot ulcer shows that out of 10 patients in experimental group, majority of 7(70%) patients age was 56 – 65 years. In control group majority of 7(63.64%) patients age was 51-60 years respectively. Carrel & Nouy (1997) first time reported that, the delay in wound healing is associated with ageing more than 50 years. They have also been reported that complications of wound healing such as wound dehiscence, are more common in the age group of 50-60 years.

The gender of patients with diabetic foot ulcer reveals that, in experimental group all were males10(100%) and in control group 8 (72.73%) were males, 3 (27.27%) were females.A retrospective cohort study conducted by Taylor & Smith, (2002) on 325 patients indicate that male gender was one of the predisposing factors to poor healing of venous ulcers.

Educational status of patients with diabetic foot ulcer reveals that 4(40%) patients in experimental group and 4 (36.36%) patients in control group had completed their higher secondary education.

Occupational status of patients with diabetic foot ulcer shows that, in experimental group majority 4 (40%) patients were coolie workers. In control group 4(36.37%) patients were unemployed respectively.

The data on smoking shows that, in experimental group 6 (60%) patients were smokers and 4 (40%) patients were non-smokers. In control group 7 (63.64%) patients were smokers and 4 (36.36%) patients were non-smokers.According to a study conducted by Silverstein (1992) documented the effects of the toxic constituents of cigarette smoke--particularly nicotine, carbon monoxide, and hydrogen cyanide--suggest potential mechanisms by which smoking may undermine expeditious wound repair. Nicotine is a vasoconstrictor that reduces nutritional blood flow to the skin, resulting in tissue ischemia and impaired healing of injured tissue. Nicotine also increases platelet adhesiveness, raising the risk of thrombotic micro vascular occlusion and tissue ischemia. . Slower healing has been observed clinically in smokers with wounds resulting from trauma, disease, or surgical procedures.

Duration of diabetes mellitus of patients with diabetic foot ulcer shows that, in experimental group, 4(40%)patients had diabetes mellitus between 7-9 years .In control group majority of 5(45.45%) patients had diabetes mellitus between 7-9 years and 4(36.37%) with more than 10 years . In the present study majority of patients had diabetes mellitus more than 7 years.A study was conducted by Bennett (2004) on analysis of risk factors for diabetic foot ulceration; the result

reveals that one of risk factors is long duration of history of diabetes mellitus. It has been shown that a positive relation exists between duration of diabetes and initial wound status score and final wound status score. i.e., as duration of diabetes mellitus increases wound status score increases indicating a slower wound healing.

Duration of foot ulcer explains that, in experimental group, majority 5(50%) patients had foot ulcer between 3-4 months.In control group 4(36.36%) patients had foot ulcer between 3-4 months, 3(27.28%) had foot ulcer between 2-3 months.

Recent fasting blood sugar value of patients with diabetic foot ulcer shows that in experimental group, 6(60%) patients had their fasting blood sugar value between 121-160 mg/dl. In control group 5(45.46%) patients had their fasting blood sugar value between 121-160 mg/dl, 4(36.36%) patients had their fasting blood sugar value between 80-120 mg/dl.

Recent glycosylated hemoglobin value of patients with diabetic foot ulcer which shows that, in experimental group 5(50%) patients had their glycosylated hemoglobin value between 7-8 and 5(50%) patients had their glycosylated hemoglobin value between 8-9. In control group majority of 7(63.63%) patients had their glycosylated hemoglobin value between 8-9and 4(36.37%) patients had their glycosylated hemoglobin value between 7-8.

5.2 Objective 1: Assess the level of wound healing among patients with diabetic Foot Ulcer.

Level of wound healing among 21patients with diabetic foot ulcer shows that, in experimental group 5(50%) patients had moderate wound healing, 2(20%) patients had maximum wound healing, 2 (20%) patients had minimal wound healing and 1(10%) had wound degeneration.In control group, majority of 6(54.55%) patients had moderate wound healing, 2 (18.18%) had maximum wound healing, 2(18.18%) patients had minimal wound healing and 1(9.09%) patient had wound regeneration.

5.3 Objective2: To evaluate the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer.

After assessing the level of wound healing among patients with diabetic foot ulcer, topical oxygen therapy was administered by the researcher for the duration of 30 minutes once daily for 10 days.

5.3.1 Level of wound healing among experimental and control group before and after intervention

Before intervention it was found that, in experimental group 5(50%) patients had moderate wound healing, 2(20%) patients had maximum wound healing, 2(20%)patients had minimal wound healing and 1(10%) had wound degeneration whereas after intervention, it was identified that,4(40%)patients had wound regeneration4(40%) patients had maximum wound healing and 2(20%)patients had moderate wound healing.

In control group, majority of 6(54.55%) patients had moderate wound healing, 2(18.18%) had maximum wound healing,2(18.18%) had minimal wound healing and 1(9.09%) patient had wound regeneration. Whereas post test results showed that,3 (27.28%) patients had maximum wound healing 4 (36.36%) had moderate wound healing and 4(36.36%)patients had minimum wound healing.

5.3.1.1 Assessment on the level of wound healing among patients with diabeticfoot ulcer in experimental group

After administration of topical oxygen therapy the level of wound healing was assessed using the same tool. The present study shows that the mean wound healing scorewas reduced from 38.9 to 24.8 with the standard deviation of 9.92 and 10.82 respectively. The calculated 't' value 7.27which was significant at 0.001 level. The result shows that a highly significant difference was found in the level wound healing among patients with diabetic foot ulcer after administration of topical oxygen therapy.

The results of the present study lies same with an study conducted by Blackman et.al with an aim to evaluate the topical oxygen therapy in treatment of diabetic foot ulcer.17 patients received topical oxygen therapy for 30 minutes for 2 weeks. Results showed that 14 out of17 wound healing has reduced from mean of 84.6 to 46.4 with a t value of 12.1 which was significant at 0.001 level of significance.

5.3.1.2 Assessment on level of wound healing among patients with diabetic foot ulcer in control group

Paired ‘t’ test was used to assess the pre test and post test level of wound healing among patients with diabetic foot ulcer. It was identified that, the mean wound score was increased from 36.6 to 38.9 with the standard deviation of 8.81 and 10.31 respectively. The calculated‘t’ value 1.35 was lesser than the table value. Hence no significant difference was not found in pretest and post test level of wound healing among patients with diabetic foot ulcer in control group.

5.3.2 Effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer

Student‘t’ test was used to find the difference in the level of wound healing among experimental and control group after intervention. It was identified that the mean level of wound healing among patients with diabetic foot ulcer in both groups was 24.8 and 38.9 respectively with a mean difference of 14.1. Likewise the standard deviation of the experimental and control group was 7.42 and 10.31 respectively. The calculated ‘t’ value was 3.38 which was greater than the table value at0.05 level of significance.. Hence the research hypothesis ‘There will be a significant difference in the level of wound healing in experimental group and control group after administration of topical oxygen therapy wasaccepted.

The result of present study goes in line with a study, conducted by Chandan (2010).He suggests that brief exposures to pure oxygen not only help chronic and other hard-to-heal wounds to heal completely, such exposures also help Diabetic wounds heal faster. The researcher implemented topical oxygen

therapy to treat 30 patients with a total of 56 wounds. The therapy required placing a bag containing pure oxygen over the wound for 30 minutes a day. More than two-thirds of the difficult wounds healed with the oxygen treatment alone. The results showed that the experimental group had significantly greater gains in topical oxygen therapy with an average rate of closure for TOT was 0.004 cm3/day which was significant at 0.05 level,with a greater decreases in wound scores from pretest to post test.

5.4 Objective3: Association between the pretest level of wound healing and selected demographic variables

It was found that chi square value for age (χ^2=21.20*), occupational status (χ^2=27.72*), educational status (χ^2=42.07*), duration of diabetes mellitus (χ^2=16.03*), duration of foot ulcer (χ^2=24.67*) had association with the level of wound healing among patients with diabetic foot ulcer at 0.05 level of significance.

History of smoking (χ^2=6.21), recent fasting blood sugar value (χ^2=12.79), glycosylated hemoglobin value (χ^2=7.46) had no association with the level of wound healing among patients with diabetic foot ulcer.

SUMMARY AND CONCLUSION

This chapter summarizes the major findings, limitations and implications in the field of nursing education, nursing practice, nursing administration, nursing research and recommendations for further research..

The study was conducted to evaluate the effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer at selected hospital, Coimbatore.

True experimental design was used for the study. General System Theory which was proposed in the year of 1968 was used as a conceptual framework for the present study. Review of literature brought out many facts about effect of topical oxygen therapy on wound healing among patients with diabetic foot ulcer.

The study was conducted in selected wards of Sri-Ramakrishna hospital Coimbatore. Bates Jensen wound assessment tool (BWAT) 2001was used to assess the level of wound healing among patients with diabetic foot ulcer.

In this study, consecutive sampling technique was used to select the samples and were randomly assigned to experimental group (n=10) and the control group (n=11). Topical oxygen therapy was administered for the samples in experimental group by the researcher. No intervention was given for control group. Post-test was done on the 11th day (next day after the last session). The data analysis was done using descriptive and inferential statistics.

6.1 Major Findings of the Study

6.1.1 In the experimental group, majority 4(40%) patients age group was between 56-60 years and in control group, majority 4 (36.36%) patients age was group between 51-55 years.

6.1.2 In the experimental group all 10(100%) were males and in the control group 8 (72.73%) were males and 3(27.27%) were females.

6.1.3 Educational status of patients with diabetic foot ulcer shows that,majority of 8(76.36%) patients in both the group also have completed their higher secondary education.

6.1.4 Occupational status shows that, in the experimental group, majority of 4(40%) patients were coolie workers. In control group majority of 4(36.37%) patientswere unemployed respectively.

6.1.5 Data on history of smoking which reveals that, in experimental group majority of 6 (60%) patients were smokers and 4 (40%) were non-smokers. In control group 7 (63.64%) patients were smokers and 4 (36.36%) were non-smokers.

6.1.6 Data on duration of diabetes mellitus shows that, majority of patients had diabetes mellitus between 7-9 years in both the groups. .

6.1.7 Data on duration of foot ulcer shows that in both experimental group and control group majority of 9(86.36%) patients had foot ulcer between 3-4 months.

6.1.8 Data on recent fasting blood sugar value shows that, majority of 6(60%) patients had their fasting blood sugar value between 121-160mg/dl. In control group majority of 5(45.46%) patients had fasting blood sugar value between 121-160 mg/dl.

6.1.9 Data on recent glycosylated hemoglobin value shows that, in experimental group majority of 5(50%) patients had glycosylated hemoglobin value between 7-8.In control group 7(63.63%) had glycosylated hemoglobin value between 8-9.

6.1.10 The study shows that the mean wound healing score was found to be reduced from 38.9 to 24.8 after topical oxygen therapy in experimental group.

6.1.11 The mean pretest and post test score of wound score was increased from 36.6and 38.9 after routine wound dressing in control group.

6.1.12 It was found that chi square value for age, occupational status, educational status, duration of diabetes mellitus, duration of foot ulcer, had association with the level of wound healing among patients with diabetic foot ulcer at 0.05 level of significance.

6.2 Limitation

6.2.1 Sample size was confined to small number which limits the generalization of the study findings. (n=21)

6.3 Recommendations

6.3.1 All staff nurses have to be trained to implement topical oxygen therapy to improve the level of wound healing among patients with diabetic foot ulcer

6.3.2 A similar study can be conducted among the people with other disorders like chronic non-healing ulcers,patients with bed sore and patients with peripheral vascular diseases and burns.

6.3.3 A study can be conducted to compare the level of wound healing among infected and non-infected wound.

6.4 Nursing Implication

6.4.1 Nursing Education

The nursing curriculum should include topical oxygen therapy as an alternative and complementary therapy, since the present study proved that it can improve the level of wound healing among patients with diabetic foot ulcer. Nurse educators need to have knowledge and awareness on topical oxygen therapy, as it is an effective measure to improve the level of wound healing. Steps should be taken to include the literature of topical oxygen therapy into nursing curriculum

6.4.2 Nursing Administration

Nurse administrators can motivate the nurses to provide topical oxygen therapy to improve the level of wound healing among patients with diabetic foot ulcer. Thereby nurses can update the knowledge about various complementary therapies which are useful for clinical practice through in-service and continuing education.

6.4.3 Nursing Practice

The nurse working in the hospitals should be trained focus to assess the level of wound healing among patients with diabetic foot ulcer and its consequences and the implementation of topical oxygen therapy to improve the level of wound healing.Topical oxygen therapy should be used adjunctively to other pharmacological treatment to promote faster wound healing.

6.4.4 Nursing Research

The study has tested the effectiveness of topical oxygen therapy on wound healing among patients with diabetic foot ulcer. It can be used as evidence based practice for improving the levelof wound healing. The nursing research need to focus more on the evidence based and holistic practice through understanding the various techniques that can bring improvement in level of wound healing among patients with diabetic foot ulcer. Similar studies can be undertaken for assessing the level of wound healing among patients with Diabetic foot ulcer in different settings.

6.5 Conclusion

The diabetic foot ulcer is the most common complication of diabetes mellitus, greater than retinopathy, neuropathy, and stroke combined.Diabetic foot ulcers at its later stages highly affect the person's quality of life and image. Topical oxygen therapy which contains the healing properties and anti microbial properties is effective in the successful management of foot ulcers in an affordable and simple way.Results showed that there was a faster wound healing with a formation of granulation tissue in experimental group and very slow wound healing in the control group. Hence, the researcher concludes that topical oxygen therapy was found to be an appropriate method for wound healing among patients with diabetic foot ulcer.

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ANNEXURE I

Analysis on The Effect of Topical Oxygen Therapy on wound healing Among Experimental And Control Group

Student 't' test was used to analyse the level of Topical Oxygen therapy on wound healing between experimental and control group

$$t = \frac{\overline{X_1} - \overline{X_2}}{SE}$$

Where,

SE (Standard Error) = SD $\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$

SD (Combined standard deviation) = $\sqrt{\frac{\sum\left(x_1 - \overline{x_1}\right)^2 + \sum\left(x_2 - \overline{x_2}\right)^2}{n_1 + n_2 - 2}}$

$\overline{X}_1$ = Mean of the experimental group

$\overline{X}_2$ = Mean of the control group post

n_1 = Number of samples in experimental group

n_2 = Number of samples in control group

ANNEXURE I- 1

Analysis on Level of wound status BeforeTopical Oxygen therapy among Experimental and control group

S.No	Experimental Group			Control Group		
	X_1	$X1-\overline{X1}=D1$	$D1^2$	X_2	$X2-\overline{X2}=D2$	$D2^2$
1.	24	-14.9	222.01	19	-17.6	309.76
2.	48	9.1	82.81	28	8.6	73.96
3.	29	-9.9	98.01	36	-0.6	0.36
4.	40	1.1	1.21	40	3.4	11.56
5.	37	-1.9	3.61	30	-6.6	43.56
6.	32	-6.9	47.61	49	12.4	153.76
7.	44	5.1	26.01	40	3.4	11.56
8.	35	-3.9	15.21	34	-2.6	6.76
9.	61	22.1	488.41	39	2.4	5.76
10.	39	0.1	0.01	36	-0.6	0.36
11.				52	15.4	237.16

$$SD = \sqrt{\frac{\sum\left(x_1-\overline{x_1}\right)^2+\sum\left(x_2-\overline{x_2}\right)^2}{n_1+n_2-2}} = \sqrt{\frac{984.9+854.56}{10+11-2}} = 9.839$$

$$SE = SD\sqrt{\frac{1}{n_1}+\frac{1}{n_2}} = 9.839\sqrt{\frac{1}{10}+\frac{1}{11}} = 4.279$$

$$t = \frac{\overline{X_1}-\overline{X_2}}{SE} = \frac{38.9-36.6}{4.279} = 0.537$$

t = 0.537

ANNEXURE I-2

Analysis on Level of wound healing After Topical Oxygen therapy among Experimental and control group

S.No	Experimental Group			Control Group		
	X_1	X1-$\overline{X1}$=D1	$D1^2$	X_2	X2-$\overline{X2}$=D2	$D2^2$
1.	16	-8.8	77.44	26	12.9	166.41
2.	39	14.2	201.64	32	-6.9	47.61
3.	19	-5.8	33.64	41	2.1	4.41
4.	29	4.2	17.64	34	4.9	24.01
5.	18	-6.8	46.24	28	10.9	118.81
6.	19	-5.8	33.64	53	14.1	198.81
7.	23	-1.8	3.24	38	-0.9	0.81
8.	27	2.2	4.84	40	1.1	1.21
9.	36	11.2	125.44	47	8.1	65.61
10.	22	-2.8	7.84	29	9.9	98.01
11.				60	21.1	445.21

$$SD = \sqrt{\frac{\sum\left(x_1-\overline{x_1}\right)^2+\sum\left(x_2-\overline{x_2}\right)^2}{n_1+n_2-2}} = \sqrt{\frac{551.6+1170.91}{10+11-2}} = 9.52$$

$$SE = SD\sqrt{\frac{1}{n_1}+\frac{1}{n_2}} = 9.52\sqrt{\frac{1}{10}+\frac{1}{11}} = 4.141$$

$$t = \frac{\overline{X_1}-\overline{X_2}}{SE} = \frac{24.8-38.9}{4.141} = 3.40$$

t = 3.40

ANNEXURE II

Analysis on difference between pretest and post test level of wound healing among both the groups

Paired 't' test was used to analyse the difference between pre and post test level of wound healing in both groups.

$$t = \frac{\bar{d}}{SE}$$

where,

$$SE = \frac{SD}{\sqrt{n}}$$

$$SD = \sqrt{\frac{\sum D^2 - \frac{\left(\sum D\right)^2}{n}}{n-1}}$$

$\bar{d}$ = Mean of difference between test score

SE = Standard Error

ΣD = Sum of mean difference between test scores

ΣD^2 = Sum of square of mean difference between the test scores

SD = Standard deviation of the test score

n = Number of samples

ANNEXURE II -1

Effect of Topical Oxygen therapy on wound healing among patients with Diabetic foot ulcer in experimental group

S.No	Pre test (x_1)	Post test (x_2)	$X_1-X_2=D$	D^2
1	24	16	8	64
2	48	39	9	81
3	29	19	10	100
4	40	29	11	121
5	37	18	19	361
6	32	19	13	169
7	44	23	21	441
8	35	27	8	64
9	61	36	25	625
10	39	22	17	289
			$\Sigma D = 141$	$\Sigma D^2 = 2315$

$$SD = \sqrt{\frac{\Sigma D^2 - \frac{(\Sigma D)^2}{n}}{n-1}} = \sqrt{\frac{2315 - \frac{(141)^2}{10}}{10-1}} = 6.11$$

$$\bar{d} = \frac{\Sigma D}{n} = \frac{141}{10} = 14.1$$

$$SE = \frac{SD}{\sqrt{n}} = \frac{6.11}{\sqrt{10}} = 1.932$$

$$t = \frac{\bar{d}}{SE} = \frac{14.1}{1.932} = 7.29$$

t = 7.29

ANNEXURE II-2

Effect of Topical Oxygen therapy on wound healing among patients with Diabetic foot ulcer in control group

S.No	Pre test (x_1)	Post test (x_2)	$X_1-X_2=D$	D^2
1	19	26	-7	49
2	28	32	-4	16
3	36	41	-5	25
4	40	34	6	36
5	30	28	2	4
6	49	53	-4	16
7	40	38	2	4
8	34	40	-6	36
9	39	47	-8	64
10	36	29	7	49
11	52	60	-8	64
			$\Sigma D = -25$	$\Sigma D^2 = 363$

$$\text{Standard Deviation} = \sqrt{\frac{\Sigma D^2 - \frac{(\Sigma D)^2}{n}}{n-1}} = \sqrt{\frac{363 - \frac{(-25)^2}{11}}{10}} = 5.53$$

$$\bar{d} = \frac{\Sigma D}{n} = \frac{25}{9} = 2.27$$

$$SE = \frac{SD}{\sqrt{n}} = \frac{5.53}{\sqrt{10}} = \frac{5.53}{3.162} = 1.748$$

$$t = \frac{\bar{D}}{SE} = \frac{2.27}{1.748} = 1.35$$

t = 1.35

ANNEXURE III

Chi-Square test analysis between the pretest level of wound score and selected demographic variables.

Chi-Square (with yates correction) test was used to check the association between the pre test level of wound status and selected demographic variables.

$$\chi^2 = \sum \frac{\left((O-E)-0.5\right)^2}{E}$$

where,

O = Observed value

E = Expected value in corresponding category

E = $\frac{RT \times CT}{N}$

RT = Row total

CT = Column total

N = Number of samples

0.5 = Yates correction value

ANNEXURE III - 1

Chi-Square test analysis between the pretest level of wound healing and age among patients with diabetic foot ulcer

Age	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
45-50	1	1	1	0	0	3
51-55	0	1	3	2	0	6
56-60	0	2	4	1	0	7
61-65	0	0	3	1	1	5
TOTAL	1	4	11	4	1	21

O	**E=$\frac{RT\times CT}{N}$**	**E**	**O – E**	**(O-E) – 0.5**	**$[(O-E)-0.5]^2$**	**$\frac{[(O-E)-0.5]^2}{E}$**
1	$E_1=\frac{3\times1}{21}$	0.14	0.86	0.36	0.129	0.9257
0	$E_0=\frac{6\times1}{21}$	0.28	-0.28	-0.78	0.608	2.1728
0	$E_0=\frac{7\times1}{21}$	0.33	-0.33	-0.83	0.688	2.0875
0	$E_0=\frac{5\times1}{21}$	0.23	-0.23	-0.73	0.532	2.3169
1	$E_1=\frac{3\times4}{21}$	0.57	0.43	-0.07	0.004	0.0086
1	$E_1=\frac{6\times4}{21}$	1.14	-0.14	-0.64	0.202	0.3592
2	$E_2=\frac{7\times4}{21}$	1.33	0.67	0.17	0.028	0.0217
0	$E_0=\frac{5\times4}{21}$	0.95	-0.95	-1.45	2.102	2.2131
1	$E_1=\frac{3\times11}{21}$	1.57	-0.57	-1.07	1.144	0.7292
3	$E_3=\frac{6\times11}{21}$	3.14	-0.14	-0.64	0.448	0.1429
4	$E_4=\frac{7\times11}{21}$	3.66	0.34	-0.16	0.025	0.0069
3	$E_3=\frac{5\times11}{21}$	2.61	0.39	-0.11	0.012	0.0046
0	$E_0=\frac{3\times4}{21}$	0.57	-0.57	-1.07	1.147	2.008
2	$E_2=\frac{6\times4}{21}$	1.14	0.85	0.35	0.128	0.112
1	$E_1=\frac{7\times4}{21}$	1.33	-0.33	-0.83	0.693	0.520
1	$E_1=\frac{5\times4}{21}$	0.95	0.04	-0.45	0.204	0.214
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.412	2.902
0	$E_0=\frac{6\times1}{21}$	0.28	-0.28	-0.78	0.616	2.162
0	$E_0=\frac{7\times1}{21}$	0.33	-0.33	-0.83	0.693	2.083
1	$E_1=\frac{5\times1}{21}$	0.23	0.76	0.26	0.068	0.288
Σx^2						21.20

ANNEXURE III - 2

Chi-Square test analysis between the pretest level of wound healing and gender among patients with diabetic foot ulcer

Gender	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
Male	1	4	9	3	1	18
Female	0	0	2	1	0	3
TOTAL	1	4	11	4	1	21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) – 0.5	$[(O-E)-0.5]^2$	$\frac{[(O-E)-0.5]^2}{E}$
1	$E_1=\frac{18\times1}{21}$	0.85	0.15	-0.35	0.1225	0.1441
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.4096	2.9257
4	$E_4=\frac{18\times4}{21}$	3.42	0.58	0.08	0.0064	0.0018
0	$E_0=\frac{3\times4}{21}$	0.57	-0.57	1.07	1.3689	2.4015
9	$E_9=\frac{18\times11}{21}$	9.42	-0.42	-0.92	0.8464	0.0818
2	$E_2=\frac{3\times11}{21}$	1.57	0.43	-0.07	0.0049	0.0031
3	$E_3=\frac{18\times4}{21}$	3.42	-0.42	-0.92	0.8464	0.144
1	$E_1=\frac{3\times4}{21}$	0.57	0.43	-0.07	0.0049	0.008
1	$E_1=\frac{18\times1}{21}$	0.85	0.15	-0.35	0.1225	0.144
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.409	2.925
Σx^2						8.493

ANNEXURE III -3

Chi-Square test analysis between the pretest level of wound healing and educational status among patients with diabetic foot ulcer

Educational status	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
Illiterate	0	1	0	0	0	1
Primary Education	1	1	3	0	0	5
Secondary Education	0	1	2	1	0	4
Higher secondary Education	0	1	5	1	1	8
Graduate	0	0	1	2	0	3
TOTAL	1	4	11	4	1	21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) –0.5	$[(\mathbf{0}-\boldsymbol{E})-\mathbf{0.5}]^2$	$\frac{[(\boldsymbol{O}-\boldsymbol{E})-\mathbf{0.5}]^2}{\boldsymbol{E}}$
0	$E_0=\frac{1\times1}{21}$	0.04	-0.04	-0.54	0.29	7.25
1	$E_1=\frac{5\times1}{21}$	0.23	0.77	0.27	0.07	6.30
0	$E_0=\frac{4\times1}{21}$	0.19	-0.19	-0.69	0.47	2.47
0	$E_0=\frac{8\times1}{21}$	0.38	-0.38	-0.88	0.77	2.02
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.40	2.85
1	$E_1=\frac{1\times4}{21}$	0.19	0.81	0.31	0.09	0.47
1	$E_1=\frac{5\times4}{21}$	0.95	0.05	-0.45	0.20	0.21
1	$E_1=\frac{4\times4}{21}$	0.76	0.24	0.26	0.06	0.07
1	$E_1=\frac{8\times4}{21}$	1.52	-0.52	-1.02	1.04	0.68
0	$E_0=\frac{3\times4}{21}$	0.57	-0.57	-1.07	1.14	2.00
0	$E_0=\frac{1\times11}{21}$	0.52	-0.52	-1.02	1.04	2.00
3	$E_3=\frac{5\times11}{21}$	2.61	0.39	-0.11	0.01	0.003
2	$E_2=\frac{4\times11}{21}$	2.09	-0.09	-0.59	0.34	0.16
5	$E_5=\frac{8\times11}{21}$	4.19	0.81	1.31	1.71	0.40
1	$E_1=\frac{3\times11}{21}$	1.57	-0.57	-1.07	1.14	0.72
0	$E_0=\frac{1\times4}{21}$	0.19	-0.19	-0.69	0.47	2.50
0	$E_0=\frac{5\times4}{21}$	0.95	-0.95	-1.45	2.10	2.21
1	$E_1=\frac{4\times4}{21}$	0.76	0.24	-0.26	0.06	0.08
1	$E_1=\frac{8\times4}{21}$	1.52	-0.52	-1.02	1.04	0.68
2	$E_2=\frac{3\times4}{21}$	1.57	0.43	-0.07	0.004	0.003
0	$E_0=\frac{1\times1}{21}$	0.04	-0.04	-0.54	0.29	7.29
0	$E_0=\frac{5\times1}{21}$	0.23	-0.23	-0.73	0.53	2.31
0	$E_0=\frac{4\times1}{21}$	0.19	-0.19	-0.69	0.47	2.50
1	$E_1=\frac{8\times1}{21}$	0.38	0.62	0.12	0.01	0.03
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.40	2.92
Σx^2						42.07

ANNEXURE III -4

Chi-Square test analysis between the pretest level of wound healing and occupation among patients with diabetic foot ulcer

Occupation	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
Coolie	1	3	2	0	0	6
Private	0	1	2	1	0	4
Government	0	0	1	2	1	4
Unemployed	0	0	6	1	0	7
TOTAL	1	4	11	4	1	21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) – 0.5	$[(O-E)-0.5]^2$	$\frac{[(O-E)-0.5]^2}{E}$
1	$E_1=\frac{6\times1}{21}$	0.28	0.72	0.22	0.048	0.172
0	$E_0=\frac{4\times1}{21}$	0.19	-0.19	-0.69	0.476	2.505
0	$E_0=\frac{4\times1}{21}$	0.19	-0.19	-0.69	0.476	2.505
0	$E_0=\frac{7\times1}{21}$	0.33	-0.33	-0.83	0.688	2.087
3	$E_3=\frac{6\times4}{21}$	1.14	1.86	1.36	1.849	1.622
1	$E_1=\frac{4\times4}{21}$	0.76	0.24	-0.26	0.06	0.078
0	$E_0=\frac{4\times4}{21}$	0.76	-0.76	-1.26	1.587	2.088
0	$E_0=\frac{7\times4}{21}$	1.33	-1.33	-1.83	3.348	2.517
2	$E_2=\frac{6\times11}{21}$	3.14	-1.14	-1.64	2.689	0.856
2	$E_2=\frac{4\times11}{21}$	2.09	-0.09	-0.59	0.348	0.166
1	$E_1=\frac{4\times11}{21}$	2.09	-1.09	-1.59	2.528	1.209
6	$E_6=\frac{7\times11}{21}$	3.66	2.34	1.84	3.385	0.925
0	$E_0=\frac{6\times4}{21}$	1.14	-1.14	-1.64	2.68	2.35
1	$E_1=\frac{4\times4}{21}$	0.76	0.24	-0.26	0.06	0.08
2	$E_2=\frac{4\times4}{21}$	0.76	1.24	0.74	0.54	0.72
1	$E_1=\frac{7\times4}{21}$	1.33	-0.33	-0.83	0.68	0.57
0	$E_0=\frac{6\times1}{21}$	0.28	-0.28	-0.78	0.60	2.17
0	$E_0=\frac{4\times1}{21}$	0.19	-0.19	-0.69	0.47	2.50
1	$E_1=\frac{4\times1}{21}$	0.19	0.81	0.31	0.09	0.50
0	$E_0=\frac{7\times1}{21}$	0.33	-0.33	-0.83	0.68	2.08
Σx^2						27.719

ANNEXURE III- 5

Chi-Square test analysis between the pretest level of wound healing and history of smoking among patients with diabetic foot ulcer

Smoking	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
Yes	1	3	7	2	0	13
No	0	1	4	2	1	8
TOTAL	1	4	11	4	1	21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) – 0.5	$[(O-E)-0.5]^2$	$\frac{[(O-E)-0.5]^2}{E}$
1	$E_1=\frac{13\times1}{21}$	0.619	0.381	-0.119	0.141	0.022
0	$E_0=\frac{8\times1}{21}$	0.380	-0.38	-0.88	0.774	2.037
3	$E_3=\frac{13\times4}{21}$	2.476	0.524	0.024	0.0005	2.326
1	$E_1=\frac{8\times4}{21}$	1.523	-0.523	-1.023	1.046	0.687
7	$E_7=\frac{13\times11}{21}$	6.809	0.191	-0.309	0.095	0.014
4	$E_4=\frac{8\times11}{21}$	4.190	-0.19	-0.69	0.476	0.113
2	$E_2=\frac{13\times4}{21}$	2.476	-0.476	-0.97	0.95	0.38
2	$E_2=\frac{8\times4}{21}$	1.523	-0.477	-0.02	0.005	0.008
0	$E_0=\frac{13\times1}{21}$	0.619	-0.619	-1.11	1.25	2.022
1	$E_1=\frac{8\times1}{21}$	0.380	0.62	0.12	0.014	0.037
Σx^2						6.21

ANNEXURE III - 6

Chi-Square test analysis between the pretest level of wound healing and duration of diabetes mellitus among patients with diabetic foot ulcer

Duration of diabetes mellitus	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
4-6 months	0	0	3	2	0	5
7-9 months	1	3	3	2	0	9
10-13 months	0	1	5	0	1	7
TOTAL	1	4	11	4	1	21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) – 0.5	$[(O-E)-0.5]^2$	$\frac{[(O-E)-0.5]^2}{E}$
0	$E_0=\frac{5\times1}{21}$	0.23	-0.23	-0.73	0.532	2.316
1	$E_1=\frac{9\times1}{21}$	0.42	0.58	0.08	0.006	0.015
0	$E_0=\frac{7\times1}{21}$	0.33	-0.33	-0.83	0.688	2.087
0	$E_0=\frac{5\times4}{21}$	0.95	-0.95	-1.45	2.102	2.213
3	$E_3=\frac{9\times4}{21}$	1.71	1.29	0.79	0.624	0.364
1	$E_1=\frac{7\times4}{21}$	1.33	-0.33	-0.83	0.688	0.517
3	$E_3=\frac{5\times11}{21}$	2.61	0.39	-0.11	0.012	0.004
3	$E_3=\frac{9\times11}{21}$	4.71	-1.71	-2.21	4.884	1.036
5	$E_5=\frac{7\times11}{21}$	3.66	1.34	0.84	0.705	0.192
2	$E_2=\frac{5\times4}{21}$	0.95	1.05	0.55	0.302	0.318
2	$E_2=\frac{9\times4}{21}$	1.71	0.29	-0.21	0.044	0.025
0	$E_1=\frac{7\times4}{21}$	133	-1.33	-1.83	3.348	2.517
0	$E_0=\frac{5\times1}{21}$	0.23	-0.23	-0.73	0.532	2.316
0	$E_0=\frac{9\times1}{21}$	0.42	-0.42	-0.92	0.846	2.015
1	$E_1=\frac{7\times1}{21}$	0.33	0.67	0.17	0.028	0.087
Σx^2						16.03

ANNEXURE III- 7

Chi-Square test analysis between the pretest level of wound healing and duration of foot ulcer among patients with diabetic foot ulcer

Duration of foot ulcer	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
0-1	0	1	2	0	0	3
1-2	0	0	1	2	0	3
2-3	0	2	3	1	0	6
3-4	1	1	5	1	1	9
TOTAL	1	4	11	4		21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) – 0.5	$[(0-E)-0.5]^2$	$\frac{[(O-E)-0.5]^2}{E}$
0	$E_0=\frac{1\times3}{21}$	0.14	-0.14	-0.64	0.409	2.929
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.409	2.925
0	$E_0=\frac{6\times1}{21}$	0.28	-0.28	0.78	0.608	2.172
1	$E_1=\frac{9\times1}{21}$	0.42	0.58	0.08	0.006	0.015
1	$E_1=\frac{3\times4}{21}$	0.57	0.43	-0.07	0.004	0.008
0	$E_0=\frac{3\times4}{21}$	0.57	-0.57	-1.07	1.144	2.008
2	$E_2=\frac{6\times4}{21}$	1.14	0.86	0.36	0.129	0.113
1	$E_3=\frac{9\times4}{21}$	0.71	-0.71	-1.21	1.464	0.856
2	$E_2=\frac{3\times11}{21}$	1.57	0.43	-0.07	0.004	0.003
1	$E_1=\frac{3\times11}{21}$	1.57	0.43	0.93	0.864	0.550
3	$E_3=\frac{6\times11}{21}$	3.14	0.14	-0.64	0.409	0.130
5	$E_5=\frac{9\times11}{21}$	4.71	0.29	-0.21	0.044	0.009
0	$E_0=\frac{3\times4}{21}$	0.57	-0.57	-1.07	1.144	2.008
2	$E_2=\frac{3\times4}{21}$	0.57	1.43	0.93	0.864	1.517
1	$E_1=\frac{6\times4}{21}$	1.14	-0.14	-0.64	0.409	0.359
1	$E_1=\frac{9\times4}{21}$	1.71	-0.71	-1.21	1.464	0.856
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.409	2.925
0	$E_0=\frac{3\times1}{21}$	0.14	-0.14	-0.64	0.409	2.925
0	$E_0=\frac{6\times1}{21}$	0.28	-0.28	-0.78	0.608	2.172
1	$E_1=\frac{9\times1}{21}$	0.42	0.58	0.08	0.006	0.015
Σx^2						24.67

ANNEXURE III - 8

Chi-Square test analysis between the pretest level of wound healing and Recent FBS value among patients with diabetic foot ulcer

Recent FBS value	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
80-120md/dl	0	1	4	1	0	6
121-160mg/dl	1	3	5	2	0	11
161-200mg/dl	0	0	2	1	1	4
TOTAL	1	4	11	4	1	21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) – 0.5	$[(O-E)-0.5]^2$	$\frac{[(O-E)-0.5]^2}{E}$
0	$E_0=\frac{6\times1}{21}$	0.285	-0.285	-0.785	0.616	2.162
1	$E_1=\frac{11\times1}{21}$	0.523	0.477	-0.023	0.0005	0.001
0	$E_0=\frac{4\times1}{21}$	0.190	-0.19	-0.69	0.476	2.505
1	$E_1=\frac{6\times4}{21}$	1.142	-0.142	-0.642	0.412	0.360
3	$E_3=\frac{11\times4}{21}$	2.095	0.905	0.405	0.164	0.078
0	$E_0=\frac{4\times4}{21}$	0.761	-0.761	-1.261	1.590	2.089
4	$E_4=\frac{6\times11}{21}$	3.142	0.858	0.358	0.128	0.040
5	$E_5=\frac{11\times11}{21}$	5.761	-0.761	-1.261	1.590	0.276
2	$E_2=\frac{4\times11}{21}$	2.095	-0.095	-0.595	0.354	0.168
1	$E_1=\frac{6\times4}{21}$	1.142	-0.142	-0.642	0.412	0.360
2	$E_2=\frac{11\times4}{21}$	2.095	-0.095	-0.595	0.354	0.168
1	$E_1=\frac{4\times4}{21}$	0.761	0.239	-0.261	0.068	0.089
0	$E_0=\frac{6\times1}{21}$	0.285	-0.285	-0.785	0.616	2.162
0	$E_0=\frac{11\times1}{21}$	0.523	-0.523	-1.023	1.046	2.001
1	$E_1=\frac{4\times1}{21}$	0.190	0.816	0.310	0.096	0.505
Σx^2						12.79

ANNEXURE III - 9

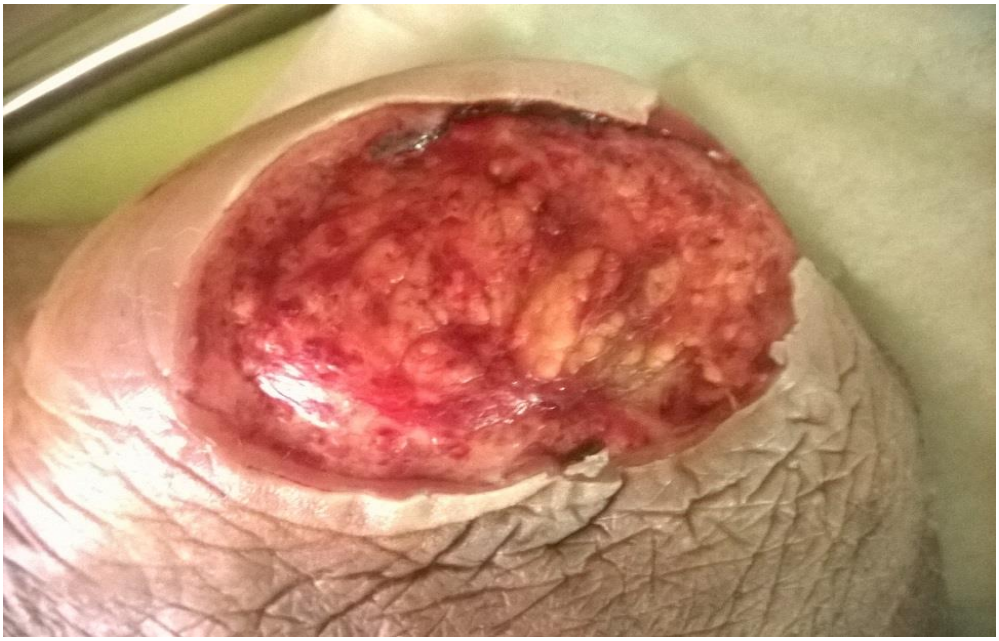
Chi-Square test analysis between the pretest level of wound healing and Glycosylated HbAIC value among patients with diabetic foot ulcer

Glycosylated HbAIC	Wound regeneration	Max.wound healing	Mod.wound healing	Min.wound healing	Wound degeneration	TOTAL
7-8	0	2	6	0	1	9
8-9	1	2	6	3	0	12
TOTAL	1	4	12	3	1	21

O	$E=\frac{RT\times CT}{N}$	E	O – E	(O-E) – 0.5	$[(O-E)-0.5]^2$	$\frac{[(O-E)-0.5]^2}{E}$
0	$E_0=\frac{9\times1}{21}$	0.428	-0.428	-0.928	0.861	2.012
1	$E_1=\frac{12\times1}{21}$	0.571	0.429	-0.071	0.005	0.008
2	$E_2=\frac{9\times4}{21}$	1.714	0.286	-0.214	0.045	0.026
2	$E_2=\frac{12\times4}{21}$	2.285	-0.285	-0.785	0.616	0.269
6	$E_6=\frac{9\times12}{21}$	5.142	0.858	0.358	0.128	0.024
6	$E_6=\frac{12\times12}{21}$	6.857	-0.857	-1.357	1.841	0.268
0	$E_0=\frac{9\times3}{21}$	1.285	-1.285	-1.785	3.186	2.471
3	$E_3=\frac{12\times3}{21}$	1.714	1.286	0.786	0.617	0.360
1	$E_1=\frac{9\times1}{21}$	0.428	0.572	0.072	0.005	0.012
0	$E_0=\frac{12\times1}{21}$	0.571	-0.517	-1.017	1.034	2.000
Σx^2						7.463

EXPERIMENTAL GROUP

BEFORE TOPICAL OXYGEN THERAPY



AFTER TOPICAL OXYGEN THERAPY

EXPERIMENTAL GROUP

BEFORE TOPICAL OXYGEN THERAPY

AFTER TOPICAL OXYGEN THERAPY

EXPERIMENTAL GROUP

BEFORE TOPICAL OXYGEN THERAPY

AFTER TOPICAL OXYGEN THERAPY

CONTROL GROUP

DIABETIC FOOT ULCER

AFTER ROUTINE DRESSING

APPENDIX-III

TOOL TO ASSESS THE EFFECT OF TOPICAL OXYGEN THERAPY ON WOUND HEALING AMONG PATIENTS WITH DIABETIC FOOT ULCER

SECTION A - DEMOGRAPHIC VARIABLE

1. AGE

a) 41-50 years

b) 51-55 years

c) 56-60 years

d) 61-65 years

2. GENDER

a) Male

b) Female

3. EDUCATION

a)Illiterate

b)Primary Education

c)Secondary Education

d)Higher Secondary Education

d)Graduate

4. OCCUPATION

a)Coolie Worker

b)Private Employee

c)Govt Employee

d)Unemployed

5. HISTORY OF SMOKING

a)Yes

b)No

6. DURATION OF DIABETES MELLITUS

a)4-6 years

b)7-9 years

c)10-13 years

7. DURATION OF FOOT ULCER

a)0-1 month

b)1-2 month

c)2-3 months

d)3-4 months

8. RECENT FASTING BLOOD SUGAR VALUE

a)80-120 mg/dl

b)121-160mg/dl

c)161-200mg/dl

9. RECENT GLYCOSYLATED HEMOGLOBIN VALUE

a)7-8

b)8-9

BATES-JENSEN WOUND ASSESSMENT TOOL

Instructions for use

General Guidelines:

Fill out the attached rating sheet to assess a wound's status after reading the definitions and methods of assessment described below. Evaluate once a week and whenever a change occurs in the wound. Rate according to each item by picking the response that best describes the wound and entering that score in the item score column for the appropriate date. When you have rated the wound on all items, determine the total score by adding together the 13-item scores. The HIGHER the total score, the more severe the wound status. Plot total score on the Wound Status Continuum to determine progress.

Specific Instructions:

1. **Size**: Use ruler to measure the longest and widest aspect of the wound surface in centimeters; multiply length x width.

2. **Depth**: Pick the depth, thickness, most appropriate to the wound using these additional descriptions:
   - 1 = tissues damaged but no break in skin surface.
   - 2 = superficial, abrasion, blister or shallow crater. Even with, &/or elevated above skin surface (e.g., hyperplasia).
   - 3 = deep crater with or without undermining of adjacent tissue.
   - 4 = visualization of tissue layers not possible due to necrosis.
   - 5 = supporting structures include tendon, joint capsule.

3. **Edges**: Use this guide:

Indistinct, diffuse	=	unable to clearly distinguish wound outline.
Attached	=	even or flush with wound base, no sides or walls present; flat.
Not attached	=	sides or walls are present; floor or base of wound is deeper than edge.
Rolled under, thickened	=	soft to firm and flexible to touch.
Hyperkeratosis	=	callous-like tissue formation around wound & at edges.
Fibrotic, scarred	=	hard, rigid to touch.

4. **Undermining**: Assess by inserting a cotton tipped applicator under the wound edge; advance it as far as it will go without using undue force; raise the tip of the applicator so it may be seen or felt on the surface of the skin; mark the surface with a pen; measure the distance from the mark on the skin to the edge of the wound. Continue process around the wound. Then use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.

5. **Necrotic Tissue Type**: Pick the type of necrotic tissue that is predominant in the wound according to color, consistency and adherence using this guide:

White/gray non-viable tissue	=	may appear prior to wound opening; skin surface is white or gray.
Non-adherent, yellow slough	=	thin, mucinous substance; scattered throughout wound bed; easily separated from wound tissue.
Loosely adherent, yellow slough	=	thick, stringy, clumps of debris; attached to wound tissue.
Adherent, soft, black eschar	=	soggy tissue; strongly attached to tissue in center or base of wound.
Firmly adherent, hard/black eschar	=	firm, crusty tissue; strongly attached to wound base and edges (like a hard scab).

6. **Necrotic Tissue Amount**: Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved.

7. **Exudate Type**: Some dressings interact with wound drainage to produce a gel or trap liquid. Before assessing exudate type, gently cleanse wound with normal saline or water. Pick the exudate type that is predominant in the wound according to color and consistency, using this guide:

Bloody	=	thin, bright red
Serosanguineous	=	thin, watery pale red to pink
Serous	=	thin, watery, clear
Purulent	=	thin or thick, opaque tan to yellow
Foul purulent	=	thick, opaque yellow to green with offensive odor

8. **Exudate Amount**: Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to determine percent of dressing involved with exudate. Use this guide:

None	=	wound tissues dry.
Scant	=	wound tissues moist; no measurable exudate.
Small	=	wound tissues wet; moisture evenly distributed in wound; drainage involves $\leq$ 25% dressing.
Moderate	=	wound tissues saturated; drainage may or may not be evenly distributed in wound; drainage involves > 25% to $\leq$ 75% dressing.
Large	=	wound tissues bathed in fluid; drainage freely expressed; may or may not be evenly distributed in wound; drainage involves > 75% of dressing.

9. **Skin Color Surrounding Wound**: Assess tissues within 4cm of wound edge. Dark-skinned persons show the colors "bright red" and "dark red" as a deepening of normal ethnic skin color or a purple hue. As healing occurs in dark-skinned persons, the new skin is pink and may never darken.

10. **Peripheral Tissue Edema & Induration**: Assess tissues within 4cm of wound edge. Non-pitting edema appears as skin that is shiny and taut. Identify pitting edema by firmly pressing a finger down into the tissues and waiting for 5 seconds, on release of pressure, tissues fail to resume previous position and an indentation appears. Induration is abnormal firmness of tissues with margins. Assess by gently pinching the tissues. Induration results in an inability to pinch the tissues. Use a transparent metric measuring guide to determine how far edema or induration extends beyond wound.

11. **Granulation Tissue**: Granulation tissue is the growth of small blood vessels and connective tissue to fill in full thickness wounds. Tissue is healthy when bright, beefy red, shiny and granular with a velvety appearance. Poor vascular supply appears as pale pink or blanched to dull, dusky red color.

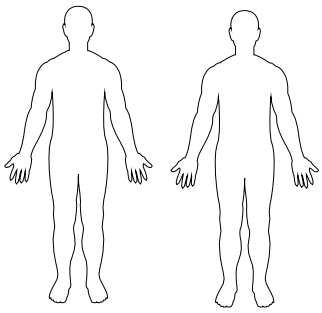
12. **Epithelialization**: Epithelialization is the process of epidermal resurfacing and appears as pink or red skin. In partial thickness wounds it can occur throughout the wound bed as well as from the wound edges. In full thickness wounds it occurs from the edges only. Use a transparent metric measuring guide with concentric circles divided into 4 (25%) pie-shaped quadrants to help determine percent of wound involved and to measure the distance the epithelial tissue extends into the wound.

BATES-JENSEN WOUND ASSESSMENT TOOL NAME

Complete the rating sheet to assess wound status. Evaluate each item by picking the response that best describes the wound and entering the score in the item score column for the appropriate date.

Location: Anatomic site. Circle, identify right **(R)** or left **(L)** and use **"X"** to mark site on body diagrams:

____ Sacrum & coccyx ____ Lateral ankle
____ Trochanter ____ Medial ankle
____ Ischial tuberosity ____ Heel Other Site



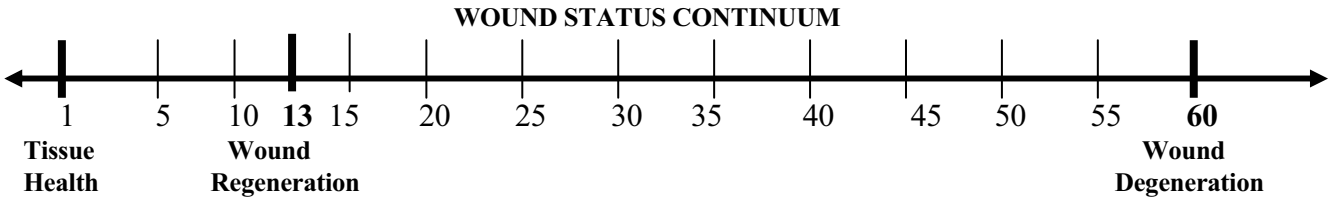
Shape: Overall wound pattern; assess by observing perimeter and depth.

Circle and date appropriate description:

____ Irregular ____ Linear or elongated
____ Round/oval ____ Bowl/boat
____ Square/rectangle ____ Butterfly Other Shape

Item	Assessment	Date Score	Date Score	Date Score
1. Size	1 = Length x width <4 sq cm 2 = Length x width 4--<16 sq cm 3 = Length x width 16.1--<36 sq cm 4 = Length x width 36.1--<80 sq cm 5 = Length x width >80 sq cm			
2. Depth	1 = Non-blanchable erythema on intact skin 2 = Partial thickness skin loss involving epidermis &/or dermis 3 = Full thickness skin loss involving damage or necrosis of subcutaneous tissue; may extend down to but not through underlying fascia; &/or mixed partial & full thickness &/or tissue layers obscured by granulation tissue 4 = Obscured by necrosis 5 = Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures			
3. Edges	1 = Indistinct, diffuse, none clearly visible 2 = Distinct, outline clearly visible, attached, even with wound base 3 = Well-defined, not attached to wound base 4 = Well-defined, not attached to base, rolled under, thickened 5 = Well-defined, fibrotic, scarred or hyperkeratotic			
4. Under-mining	1 = None present 2 =Undermining < 2 cm in any area 3 = Undermining 2-4 cm involving < 50% wound margins 4 = Undermining 2-4 cm involving > 50% wound margins 5 = Undermining > 4 cm or Tunneling in any area			
5. Necrotic Tissue Type	1 = None visible 2 = White/grey non-viable tissue &/or non-adherent yellow slough 3 = Loosely adherent yellow slough 4 = Adherent, soft, black eschar 5 = Firmly adherent, hard, black eschar			
6. Necrotic Tissue Amount	1 = None visible 2 = < 25% of wound bed covered 3 = 25% to 50% of wound covered 4 = > 50% and < 75% of wound covered 5 = 75% to 100% of wound covered			
7. Exudate Type	1 = None			

Item	Assessment	Date Score	Date Score	Date Score
	2 = Bloody 3 = Serosanguineous: thin, watery, pale red/pink 4 = Serous: thin, watery, clear 5 = Purulent: thin or thick, opaque, tan/yellow, with or without odor			
8. Exudate Amount	1 = None, dry wound 2 = Scant, wound moist but no observable exudate 3 = Small 4 = Moderate 5 = Large			
9. Skin Color Sur-rounding Wound	1 = Pink or normal for ethnic group 2 = Bright red &/or blanches to touch 3 = White or grey pallor or hypopigmented 4 = Dark red or purple &/or non-blanchable 5 = Black or hyperpigmented			
10. Peripheral Tissue Edema	1 = No swelling or edema 2 = Non-pitting edema extends <4 cm around wound 3 = Non-pitting edema extends ≥4 cm around wound 4 = Pitting edema extends < 4 cm around wound 5 = Crepitus and/or pitting edema extends ≥4 cm around wound			
11. Peripheral Tissue Induration	1 = None present 2 = Induration, < 2 cm around wound 3 = Induration 2-4 cm extending < 50% around wound 4 = Induration 2-4 cm extending ≥ 50% around wound 5 = Induration > 4 cm in any area around wound			
12. Granu-lation Tissue	1 = Skin intact or partial thickness wound 2 = Bright, beefy red; 75% to 100% of wound filled &/or tissue overgrowth 3 = Bright, beefy red; < 75% & > 25% of wound filled 4 = Pink, &/or dull, dusky red &/or fills ≤ 25% of wound 5 = No granulation tissue present			
13. Epithe-lializa-tion	1 = 100% wound covered, surface intact 2 = 75% to <100% wound covered &/or epithelial tissue extends >0.5cm into wound bed 3 = 50% to <75% wound covered &/or epithelial tissue extends to <0.5cm into wound bed 4 = 25% to < 50% wound covered 5 = < 25% wound covered			
	TOTAL SCORE			
	SIGNATURE			



Plot the total score on the Wound Status Continuum by putting an **"X"** on the line and the date beneath the line. Plot multiple scores with their dates to see-at-a-glance regeneration or degeneration of the wound.